Summary of Safety and Clinical Performance (SSCP)

for the class III medical device group

Neurovascular Stent

consisting of

pEGASUS and pEGASUS HPC

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Basic UDI-DI:	426012378NeuroStentTE

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Purpose of the summary report on safety and clinical performance

The purpose of the Summary of Safety and Clinical Performance (= SSCP) is to explain the most important information about the safety and clinical performance of the medical device group Neurovascular Stent to the reader, both healthcare professionals and patients or lay persons, in a comprehensible way. This report will help to ensure that the public has adequate access to information about the medical device group Neurovascular Stent.

The SSCP is not intended to provide general advice on the diagnosis or treatment of aneurysms or atherosclerotic vascular stenosis nor to replace the Instructions for Use (IFU) as the primary document provided to ensure the safe use of the medical device group Neurovascular Stent.

Beginning with page 7, information about the medical device group Neurovascular Stent is summarized for the **physician, the intended medical user** of the medical device group and **other healthcare professionals**.

Beginning with page 22, information about the medical device group Neurovascular Stent is summarized for the **patient** and **lay persons**.

The chapter "**Bibliography**" gives an overview of the known scientific literature and publications relating to the medical device group Neurovascular Stent and also regarding the referenced literature throughout this SSCP.

This SSCP has been validated by the Notified Body DQS (see chapter 1.9) in English language. This version was used as the basis for translation into other EU languages. The SSCP is regularly updated in Eudamed.

Terms, abbreviations and definitions

Terms	Definition
ASA	Acetylsalicylic acid
Basic UDI-DI	Basic Unique Device Identification – Device Identifier. The Basic UDI-DI is a root category for a specific device family. Many UDI-DIs can be associated with one basic UDI-DI.
BfArM	The German Federal Institute for Drugs and Medical devices (German: Bundesinstitut für Arzneimittel und Medizinprodukte) is an organizationally independent higher federal authority with its headquarters in the city of Bonn/Germany.
CE-certification	The CE (Conformité Européenne) marking of a medical device shows its complete compliance with legal requirements.
Clinical Evaluation	A Clinical Evaluation is a systematic collection and evaluation of clinical data from a wide variety of sources. The manufacturer is obliged to conduct a Clinical Evaluation during the entire life cycle of a medical device. Thus, a Clinical Evaluation also includes a clinical follow-up of the medical device in the market.
CS	Common Specifications are a set of standards provided by European Commission that have to be applied by manufacturers where no or insufficient harmonized standards exist.
DQS	The DQS (Deutsche Gesellschaft zur Zertifizierung von Qualitätssicherungssystemen = German Association for the certification of quality assurance systems) is a Notified Body.
EMDN	European Medical Device Nomenclature (EMDN Code) is the nomenclature that is used by the manufacturers when registering their Medical Devices in the Eudamed database.

Terms	Definition
Eudamed	European Database on Medical Devices (https://ec.europa.eu/tools/eudamed) – Eudamed will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). Eudamed aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.
FDA	Food and Drug Administration is a federal agency of the United States, that controls and supervises the safety of food, tobacco, and medical products.
FDA-MAUDE	The Food and Drug Administration-Manufacturer and User Facility Experience is a website by the FDA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) where Manufacturers and Users can report issues regarding specific products.
FSCA	A Field Safety Corrective Action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a field safety notice.
FSN	A Field Safety Notice is a communication sent by a manufacturer to users or customers in relation to a corrective action taken by the manufacturer to prevent or reduce the risk of a serious incident.
GSPR	The manufacturers of medical devices have to establish conformity with the General Safety and Performance Requirement and should provide sufficient evidence to demonstrate compliance with GSPR.
ICAS	Intracranial atherosclerotic stenosis
IFU	Instructions For Use
Legacy Device	A medical device that was approved by a Notified Body under the so-called Medical Device Directive (MDD) and can be placed on the market without being newly CE-certified according to Medical Device Regulation (MDR) during a limited transition period.
MDD	Medical Device Directive (MDD, 93/42/EEC). The MDD was the most important regulatory instrument for demonstrating the safety and medical-technical performance of medical devices in the European Economic Area until the Medical Device Regulation (MDR) was introduced (valid until 26.05.2021).
MDR	Medical Device Regulation (MDR, Regulation (EU) 2017/745). This Regulation covers the placing on the market, making available on the market and putting into service of medical devices and accessories intended for human use (beginning as of 27.05.2021).
mRS	The modified Rankin Scale is a scale used to determine the degree of disability after a stroke. On this scale, 0 equals no symptoms after the stroke and 6 refers to death.
NIHSS	National Institutes of Health Stroke Scale score
Notified Body	Notified Bodies of the European Union are officially designated and supervised authorities. The Notified Bodies ensure that uniform criteria related to a medical device are fulfilled throughout Europe (so-called conformity assessment procedure).
PMCF	The Post-Market Clinical Follow-Up is a systematic and proactive method of gathering clinical data on the safety and performance of CE-marked medical device.
SAH	Subarachnoid hemorrhage is bleeding in the space between the brain and the surrounding membrane (subarachnoid space).
SRN	A Single Registration Number is assigned to all medical device legal manufacturers, authorized representatives, system/procedure pack producers and importers involved in placing medical devices and in vitro diagnostics (IVD) on the European market. It is

Terms	Definition
	the primary means of identifying these so-called “Economic Operators” (EO) in the Eudamed database.
Technical Documentation	The term Technical Documentation summarizes all information and documents that describe a product (such as a medical device) and explain its use and functionality. The Technical Documentation is understood as an essential part of the product.
UDI	The Unique Device Identification is a unique numeric or alphanumeric code for a medical device. It enables clear and unambiguous identification of certain products on the market and facilitates their traceability.
UDI-DI	Unique Device Identification – Device Identifier The Unique Device Identifier (UDI) is a unique numeric or alphanumeric code for a medical device. It enables clear and unambiguous identification of specific products on the market and facilitates their traceability. Every UDI-DI is associated with only one Basic UDI-DI.

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Neurovascular Stent

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pEGASUS and pEGASUS HPC

Physicians and medical users and other healthcare professionals

Summary of Safety and Clinical Performance for physicians and medical users and other 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 medical device group Neurovascular Stent.

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

The following information is intended for the physician and medical user of the medical device group Neurovascular Stent and other healthcare professionals.

1 Device identification and general information

1.1 Device trade name(s)

The medical device group Neurovascular Stent consists of the variants pEGASUS (bare) and pEGASUS HPC (coated) (refer to Table 1). The device version with the suffix "HPC" carries a hydrophilic polymer coating. In this document, the term pEGASUS (HPC) is used for the description of both device variants. For a detailed description please refer to chapter 3.

Table 1: Classification of the medical device group Neurovascular Stent.

Medical device group	Neurovascular Stent	
Basic UDI-DI	426012378NeuroStentTE	
Product family	pEGASUS (HPC)	
Design variant	pEGASUS	pEGASUS HPC
Trade name	pEGASUS Stent System	pEGASUS HPC Stent System
Structure of REF*	PEGASUS-XXX-XX	PEGASUS-XXX-XX-HPC

*1: XXX - Max. insertion vessel-Ø; 2: XX – Length in max. insertion vessel -Ø; HPC: Coating

1.2 Manufacturer's name and address

phenox GmbH
Lise-Meitner-Allee 31
44801 Bochum
Germany
Tel.: +49 (0)234 36 919-0
Fax: +49 (0)234 36 919-19
E-Mail: info@wallabyphenox.com
Website: www.phenox.net

1.3 Manufacturer's single registration number (SRN)

The single registration number (SRN) is **DE-MF-000006524**.

1.4 Basic UDI-DI (Device identification number)

The device identification number, also known as “Basic UDI-DI” (Basic Unique Device Identification - Device Identifier), is used to identify and register medical devices in the European Union market. The Basic UDI-DI for the medical device group Neurovascular Stent is **426012378NeuroStentTE**.

1.5 Medical device nomenclature description/text

According to the European Medical Device Nomenclature (MDR 2017/745, Article 26) (EMDN), the medical device group Neurovascular Stent belongs to **EMDN P070402 „Vascular Stents“**.

1.6 Class of device

The devices of the medical device group Neurovascular Stent are classified as **Class III medical devices** according to Annex VIII, Rule 8 , second indent of the Medical Device Regulation (MDR) 2017/745.

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

pEGASUS (HPC) was initially CE-certified under the requirements of the Medical Device Directive (MDD) 93/42/EEC. The respective certification date and CE-certificate number according to the Medical Device Directive (MDD) 93/42/EEC are listed in Table 2. The certification according to the requirements of the Medical Device Regulation (MDR) 2017/745 was granted in September 2024.

Table 2: Certification dates and CE-certificate number.

Regulatory background	Product variant	First CE-certification	Certificate number
MDD	pEGASUS	22.02.2021	549256 MRA
	pEGASUS HPC		
MDR	pEGASUS	18.09.2024	31625664 MDR2017P
	pEGASUS HPC		

1.8 Authorized representative if applicable; name and the SRN

Not applicable.

1.9 Notified Body’s name and the Notified Body’s single identification number

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main
Germany
Tel.: +49 69 95427 300
Fax: +49 69 95427 388
E-Mail: medizinprodukte@dqs-med.de
Website: www.dqs-med.de
Single identification number: 0297

2 Intended use of the device

2.1 Intended purpose

The medical device pEGASUS (HPC) Stent System is a self-expanding, tubular vascular implant and allows the endovascular reconstruction of diseased arteries in the cervical and intracranial course.

The implants of the design variant pEGASUS HPC also have a hydrophilic polymer coating, which initially reduces the adhesion of thrombocytes and thus reduces the risk of thrombus formation (based on *in vitro* data [1]).

2.2 Indication(s) and target population(s)

As described in the Instructions for Use (IFU), the devices are used for the endovascular treatment of vascular diseases such as:

- saccular and fusiform aneurysms and pseudoaneurysms in combination with coils and
- atherosclerotic vascular stenosis of intracranial arteries.

Patients are not eligible for treatment when they have one of the aspects listed in the contraindications (see chapter 2.3). The products are only intended for adult persons 16 years and over.

2.3 Contraindication(s) and/or limitations

Patients with an inadequate antiplatelet therapy or insufficient anticoagulant treatment according to standard medical practice before, during, and after the treatment.

Angiography demonstrates the anatomic conditions are not appropriate for endovascular treatment, such as severe vessel tortuosity or severe stenosis.

3 Device description

3.1 Description of the device

pEGASUS (HPC) stent is a tubular vascular implant (6) that consists of an open-cell design (Figure 1). The distal and proximal ends of the implant are each equipped with three platinum markers (5) for visibility under X-ray fluoroscopy.

Each segment of the open-cell structure consists of eight crowns and the segments are connected by three connection zones. The distal and the proximal rings are completely closed. The detailed structure of pEGASUS (HPC) is presented in Figure 1 and Figure 2.

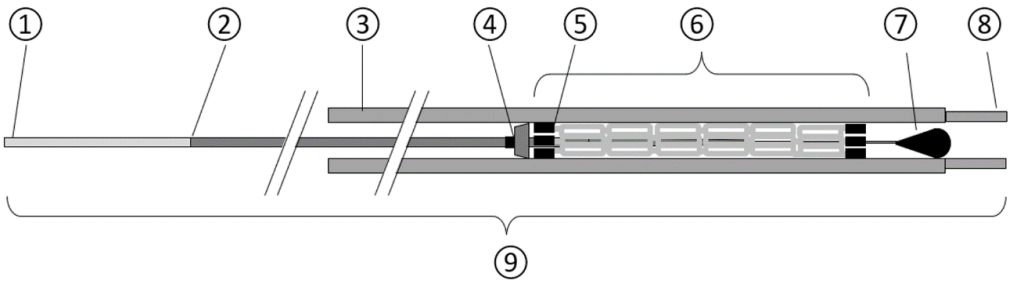

Figure 1: pEGASUS (HPC) implant and delivery system in introducer sheath.

The delivery system has a radiopaque marker at the distal wire tip (7) and another one at the bumper (4) to allow the operator to determine its position.

The implant can be advanced using the bumper (4), as long as it is in the introducer sheath (3/8) or the microcatheter. Withdrawal of the implant is not possible at any stage. The product is stored in an introducer sheath (3/8) and is transferred into a microcatheter with an inside diameter of 0.0165/0.017 inches (0.42/0.43 mm).

A colored area at the proximal end of the delivery wire (1) (without green coating) acts as a so-called "Fluorosafe Marker" (2) and identifies (as long as the introducer sheath remains on the delivery wire and is in the hemostatic valve of the microcatheter) the position to which the device can be advanced inside the microcatheter without the device tip leaving the microcatheter. When the marker (2) has reached the introducer sheath while it is being advanced, it must be pulled off and work continued under X-ray fluoroscopy.

The implant (6) self-expands as it leaves the microcatheter and cannot be withdrawn (Figure 2). When the microcatheter is withdrawn, the implant is completely released and thus detached from the delivery system (9).

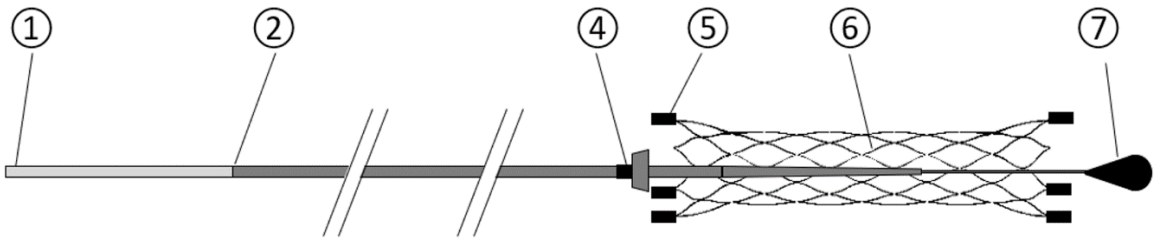

Figure 2: Delivery system and detached pEGASUS (HPC) implant.

HPC (Hydrophilic Polymer Coating)

The hydrophilic polymer coating is made of a biomimetic polymer and is designed to mimic the natural lining of the inner vessel wall, the glycocalyx layer, which is a surface that platelets do not adhere to. *In vitro* test results [1] demonstrate that the HPC coating can provide an initially reduced surface thrombogenicity.

If justified by individual circumstances, the initially reduced thrombogenicity may allow the implantation under single antiplatelet medication [2]. As stated in the IFU, additional information on current medication recommendations and experience with the medical device group Neurovascular Stent (with and without HPC) can be found on our website (refer to section 1.2) if available and in the current scientific literature.

Principles of Operations

pEGASUS (HPC) is an implantable, self-expanding stent that is placed in an intracranial or cervical artery to support the vessel wall. In the case of a diseased vessel wall, the stent(s) is/are placed over the compromised area to provide mechanical support to the vessel wall. Regarding stent-assisted coiling, the stent is implanted below the neck of an aneurysm to hold back the coil mass that is subsequently inserted into the aneurysm.
pEGASUS (HPC) in an open-cell stent.

The device is equipped with platinum markers that are visible under fluorescent X-ray imaging to visualize the stent and ensure correct stent placement.

Materials in contact with the patient

Materials that come in contact with the central circulatory system of the patient are listed in Table 3.

Sterilization

The product is intended for single use only. pEGASUS (HPC) is sterilized with ethylene oxide.

Table 3: Materials that come in contact with patient during the intervention.

Device (Long term contact)	Insertion system (Short term contact)
- Nickel-Titanium Alloy - Platinum-Iridium Alloy - If applicable: HPC (Hydrophilic Polymer Coating)	- Nickel-Titanium Alloy - Platinum-Iridium Alloy - Stainless Steel - Polytetrafluoroethylene (PTFE)

Design variations and device sizes

Table 4 shows the current model sizes of the two design variants of pEGASUS (HPC). Also, dimensions of the device when in use, are listed in this table.

Table 4: Design variations and device sizes of pEGASUS (HPC).

REF (model size)	UDI-DI	Ø, relaxed [mm]	max. vessel Ø [mm]	min. vessel Ø [mm]	Effective length [mm]
PEGASUS-350-15	04260123784645	4	3.5	2.5	15
PEGASUS-350-20	04260123784652				20
PEGASUS-350-25	04260123784669				25
PEGASUS-350-30	04260123784676				30
PEGASUS-450-15	04260123784683	5	4.5	3.5	15
PEGASUS-450-20	04260123784690				20
PEGASUS-450-25	04260123784706				25
PEGASUS-450-30	04260123784713				30
PEGASUS-350-15-HPC	04260123784720	4	3.5	2.5	15
PEGASUS-350-20-HPC	04260123784737				20
PEGASUS-350-25-HPC	04260123784744				25
PEGASUS-350-30-HPC	04260123784751				30
PEGASUS-450-15-HPC	04260123784768	5	4.5	3.5	15
PEGASUS-450-20-HPC	04260123784775				20
PEGASUS-450-25-HPC	04260123784782				25

REF (model size)	UDI-DI	Ø, relaxed [mm]	max. vessel Ø [mm]	min. vessel Ø [mm]	Effective length [mm]
PEGASUS-450-30-HPC	04260123784799				30

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

Both device variants pEGASUS and pEGASUS (HPC) got CE mark under MDD requirements (93/42/EEC) on 22.02.2021 as well as under MDR requirements (2017/745) on 18.09.2024. The product has no novel design features.

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

The products have no accessories.

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

pEGASUS (HPC) is compatible with equipment commonly used in interventional neuroradiology. This includes an angiography system, as well as sheaths, guide wires, microcatheters and other products for minimally invasive implantation of the device.

Specifically, pEGASUS (HPC) is compatible with the following microcatheters:

Table 5: Microcatheter compatibility with pEGASUS (HPC).

Product family	Microcatheter	ID
pEGASUS (HPC)	Headway 17 (MicroVention)	0.017"
	Echelon 10 (EV3/Medtronic)	0.017"

4 Risks and warnings

In addition to the contraindications described in chapter 2.3, undesirable effects, residual risks as well as warnings must be taken into account.

4.1 Residual risks and undesirable effects

The general terms risk and harm, residual risks and undesirable effects are defined as follows:

- ***Risk*** means the "combination of the probability of occurrence of harm and the severity of that harm".
- ***Harm*** is the "injury or damage to the health of people or damage to property or the environment".
- ***Undesirable effects*** "can be understood as any undesirable side-effect related to the device and that is experienced by the patient and/or can be diagnosed and/or measured in the patient".
- ***Residual risks*** are defined as a "risk remaining after risk control measures have been taken".

Residual risks and undesirable effects related to the use of neurovascular stents or the procedure, and their probability of occurrence are listed in Table 6 .

Table 6: Residual risks and undesirable effects related to the use of neurovascular stents and the procedure.

Complications/Risks/Side effects	Clinical data of pEGASUS (HPC) (%)
Air embolism	Not specifically reported
Allergic reaction	0.42% (not related to pEGASUS (HPC) but the contrast media; PMCF-data)
Coil herniation/ Coil protrusion	0% ([3] & [4] - 3.80%/2.95% (PMCF-data: 9 cases but 2 were reversible)
Cerebral hyperperfusion syndrome	Not specifically reported
Death	3.38% (PMCF-data) - 8.3%* [3]
Dissection	0% [4] – 8.1% [5]
Emboli	0.42% (PMCF-data) – 4.9% [5]
Encephalopathy	0.42% (PMCF-data)
Extravasation	0.42% (PMCF-data) - 2.7% [5]
Hemorrhage/ Hemorrhagic complication/ Internal bleeding	0% [4] - 1.26% (PMCF-data)
Hematoma	Not specifically reported
Hydrocephalus	Not specifically reported
Infection	Not specifically reported
In-stent stenosis	0.84% (PMCF-data) – 11.1% [3]
Intimal hyperplasia	Not specifically reported
Ischemia/ischemic complications	1.9% [4] - 4.64% (PMCF-data)
Neurological deficit including the consequences of a stroke	5.06% (PMCF-data)
Occlusion	Not specifically reported
Perforation	0% [3, 4]
Persistent vegetative state	0.84% (PMCF-data)
Pseudoaneurysm	0.42% (PMCF-data)
Recanalization (Aneurysm treatment)	Not specifically reported
Restenosis/Recurrent ischemic or hemorrhagic stroke (in stenosis treatment)	Not specifically reported
Retreatment (Aneurysm treatment)	Not specifically reported
Rupture	Not specifically reported
Space-occupying infarction	2.95% (PMCF-data)
Stent thrombosis/ In-stent thrombosis	1.9% [4] - 8.3% [3]
Stroke (ischemic or hemorrhagic)	4.64% (PMCF-data) - 8.3% [3]
Thrombosis/ Thromboembolic complications	1.69% (PMCF-data)
Vasospasm	0.84% (PMCF-data)
Vessel stenosis	Not specifically reported

Complications/Risks/Side effects	Clinical data of pEGASUS (HPC) (%)
Technical Complications	**Clinical data of pEGASUS (HPC) (%)**
Friction during application of the product	0.2% (Complaints) - 3.0% (PMCF-data)
Fracture of implant and/or delivery system before or during the intervention	Not reported in PMCF clinical data
Inadequate size/shape of the implant	0.5% (PMCF-data)
Unintentional release of the implant at an unplanned localization	2.5% (PMCF-data)
Detachment or deployment problems	0.1% (Complaints) - 3.85% [4]
Incomplete opening of the implant	Not reported in PMCF clinical data
Separation failure	0.1% (Complaints)
Migration of implant	Not reported in PMCF clinical data
Stent-coil combination issues	3.8% (PMCF data)

*1 patient died (1/12; 8.3%) due to pre-existing subarachnoid hemorrhage (SAH) [emergency case]; not procedure-related

Neurological deficits may include cognitive changes, convulsion/seizures, aphasia/dysphasia, headache, paralysis, paresis, numbness, paresthesia and altered state of consciousness.

4.2 Warnings and precautions

Warnings

- All manipulations must be carried out under fluoroscopic visualization.
- Do not push the device distally into the vessel once the distal tip has left the microcatheter, either during or after deployment. This can lead to a dissection or perforation of the target vessel.
- Do not retract the pEGASUS (HPC) through implanted vascular implants.
- Persons with known hypersensitivity to Nickel-Titanium materials or the materials listed in chapter “Materials to come in contact with the patient during the intervention” may suffer an allergic reaction to the pEGASUS (HPC).
- The delivery system and, where necessary, packaging components must be disposed appropriately in marked containers. Failure to dispose of the product correctly can lead to an increased risk of infection for the physician or patient.
- The product is intended for single use only. Do not reuse in another patient. Do not reprocess or resterilize. Reprocessing and re-sterilization increase the risks of patient infection and/or death as well as compromised device performance.
- Do not use if packaging is damaged or opened unintentionally, as sterility cannot be assumed otherwise. The damaged or unintentionally opened product must be exchanged and replaced with an undamaged/unopened product.
- Keep away from sunlight. Store in a dry place. The safe upper limit for short-term (<72 hrs.) temperature deviations is 60 °C and the lower limit for short term (<72 hrs.) temperature deviations is -30 °C (during transport). Exceeding the upper and lower limit may affect the performance of the product. In case these conditions cannot be met, the product should be exchanged and replaced with a product that was not exposed to the aforementioned conditions. Recommended conditions for storage: cool (15-25 °C), dark and dry.
- Placement of multiple pEGASUS (HPC) may increase the risk of ischemic complications.
- Use is only permissible prior to the expiration date, as sterility is not guaranteed otherwise.
- The device is only conditionally compatible with magnetic resonance imaging (MRI). See chapter “MRI Safety Information” for more detailed information. The values stated in the chapter “MRI Safety Information” should not be exceeded.
- The device is only for use in fully grown blood vessels. Implantation in blood vessels that are not fully grown

may lead to long term stenosis.

Precautions

- Do not use the pEGASUS (HPC) for purposes other than the intended purpose.
- Do not push the pEGASUS (HPC) out of the introducer sheath prior to initial use to inspect it. Withdrawal of the implant into the introducer sheath is not possible at any stage.
- The device must be checked for damage before use (while still in its introducer sheath). Do not use deformed or damaged devices, as function cannot be assumed otherwise.
- Microcatheters with other inner diameters (ID) than 0.0165-0.0170 inches (e.g. 0.021 or 0.027 inch) are not suitable. pEGASUS (HPC) used in microcatheters with larger IDs leads to premature detachment of the implant inside the microcatheter.
- For flushing, place the introducer sheath of the pEGASUS (HPC) inside the hemostatic valve of the microcatheter and flush it by the help of the connected irrigation fluid. Thorough flushing of the introducer sheath is essential in order to remove any trapped air bubbles.
- If the pEGASUS (HPC) system can be advanced into the microcatheter only with great effort or navigation through the microcatheter is only possible with great effort, remove the entire pEGASUS (HPC) system together with the microcatheter. Do not attempt to pull the deployed implant back through the vessel.
- The pEGASUS (HPC) is a delicate implant and requires careful handling. Never push the microcatheter onto the pEGASUS (HPC) against resistance. Never twist the delivery system. If necessary, remove the pEGASUS (HPC) together with the microcatheter.
- The pEGASUS (HPC) is unable to be withdrawn through the microcatheter or within the introducer sheath, only advancement is possible. Nevertheless, if the implant must be withdrawn at any point while the device is still inside the microcatheter, the entire pEGASUS (HPC) system must be removed from the patient together with the microcatheter.
- Forceful pulling, pushing or twisting on the delivery system may inadvertently detach the pEGASUS (HPC) from the delivery system. In such a case, the user must carefully weigh the risks of a recovery with a foreign body retrieval device against those of leaving the implant in the vessel.
- Extreme stress to the delivery system tip could lead to separation of some of its parts. In such cases, recovery with a foreign body retrieval device is recommended.
- Any additional treatment (e.g. coiling of the aneurysm while the associated microcatheter is “jailed” by the deployed pEGASUS (HPC)) should be done after pEGASUS (HPC) detachment.
- Time between start of implant deployment and complete deployment resulting in a detachment must be as short as possible, in order to prevent any bonding effects by blood ingredients and ultimately poor proximal implant deployment. This is especially relevant, if there is the risk that the patient is unresponsive or not fully responding to dual antiplatelet therapy.
- If vasospasm is suspected in the affected vascular region, all necessary measures, e.g. medication, should be used to aid regression prior to implantation.
- For delivery wire withdrawal use a separate torque device locked to the delivery wire. A suitable torquer is compatible with microguidewires that are 0.014 or 0.016 inches (0.36 or 0.41 mm) in diameter.
- If the implant has started to be released at an unwanted location, it may be safer to completely release the implant and to implant a second pEGASUS (HPC) at the desired location.

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

Up until now, no field safety corrective action (FSCA) including field safety notice (FSN) had to be initiated for the MDD-CE-certified devices.

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

The following text summarizes the results of the Clinical Evaluation and results of the post-market clinical follow-up (PMCF). The systematic literature search conducted in this process considers published data as well as other relevant data sources (e.g., studies, guidelines) on the clinical safety and performance of the medical device group Neurovascular Stent. Both favorable and unfavorable data regarding conformity with the general safety and performance requirements (GSPRs) of all devices of the medical device group Neurovascular Stent are objectively considered.

5.1 Summary of clinical data related to equivalent device

pEGASUS HPC is equivalent to pEGASUS. Any identified differences with regard to clinical, technical, and biological characteristics were analyzed and none of these differences were determined to significantly affect clinical safety or performance. Therefore, clinical data provided are applicable to all equivalent device configurations.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

Prior to MDR-CE certification, no clinical study was conducted as sufficient clinical evidence was generated with the MDD-CE certified devices ("legacy devices").

The clinical data of the legacy devices demonstrate that pEGASUS (HPC) is effective and safe for its intended purpose when used as per the Instruction For Use (IFU).

5.3 Summary of clinical data from other sources, if applicable

A total of 6 articles have been published on the use of pEGASUS (HPC).

First author	Title of publication	Year of publication
Boxberg	Initial Experience with a New Self-Expanding Open-Cell Stent System with Antithrombotic Hydrophilic Polymer Coating (pEGASUS Stent) in the Treatment of Wide-Necked Intracranial Aneurysms	2024
Lobsien	The pEGASUS- HPC stent system for stent- assisted coiling of cerebral aneurysms: a multicenter case series	2024
Pedowski	Rescue Stenting of Isolated Middle Cerebral Artery (MCA) Dissections (MCAD) with Antithrombogenic Coated Stents and Mono-Antiplatelet Therapy (MAPT)	2024
Pielenz	The pEGASUS- HPC stent system for intracranial arterial stenosis: a single- center case series	2024

5.4 An overall summary of the clinical performance and safety

Based on own clinical data on 164 cases and follow-up data on 72 cases, a successful implantation was documented in overall 99.51% of cases. In majority of cases (60.53%), a stasis of contrast was observed directly after the procedure. A complete occlusion and residual aneurysm neck were achieved in 34.21% and 5.26% of cases, respectively. At mid-term follow up (3-6 months), an adequate aneurysm occlusion rate, which is defined as complete occlusion or neck remnant, of 94.0% was reported. One of the highest number of complications

were documented due to thromboembolism which is a well-known complication of implantation of foreign bodies into arteries. Therefore, prior and following implantation of the device, antiplatelet medication is necessary to reduce the risk of thromboembolic events. The effective inhibition of platelet function should be verified by an appropriate test (e.g., Multiplate or VerifyNow or PFA). In case of discrepant findings, additional tests are strongly recommended.

All phenox known clinical data, as well as published and unpublished data were considered in this Summary of Safety and Clinical Performance (SSCP).

A critical assessment of the intended benefits of pEGASUS (HPC) compared to the risks described in chapter 4, leads to the conclusion that the benefits clearly outweigh the identifiable risks, as neurovascular stents are a well-known technology. Based on this benefit-risk assessment and own clinical experience reported in chapter 5, it can be concluded that the pEGASUS (HPC) devices are safe and effective for the intended purpose.

5.5 Ongoing or planned post-market clinical follow-up (PMCF)

As part of the post-market clinical follow-up (PMCF), clinical data are proactively and systematically collected and analyzed on the basis of the indications, contraindications and intended purpose of the products of the medical device group Neurovascular Stent. This includes e.g., market feedback (e.g., customer complaints), literature analysis of phenox´s own products as well as literature and clinical data analysis regarding similar devices and analysis of safety databases (e.g., Germany: BfArM, USA: FDA). Furthermore, a prospective, multicenter, single-arm clinical trial to evaluate the safety and efficacy of pEGASUS stent system for assisted endovascular treatment of intracranial aneurysms is ongoing (ClinicalTrials.gov: NCT06158087).

6 Possible diagnostic or therapeutic alternatives

In addition, endovascular treatment with vascular stents, the following alternative treatments are available.

6.1 Aneurysm treatment

Intracranial aneurysms can be accessed surgically (i.e., clipping) or by conventional endovascular methods (e.g., coiling alone, flow diversion).

Clipping is an open microsurgical operation in which the skull is opened under anesthesia (craniotomy). The aneurysm is located under the surgical microscope and isolated from the supporting vessel with a clip, e.g., a titanium clip. The skull bone is reinserted, and the resulting wound is closed. Microsurgical clipping has a high rate of complete aneurysm occlusion and a low rate of aneurysm rupture. However, microsurgical clipping is associated with a higher risk of adverse events such as neurologic deficits, cranial nerve palsy, infection, and prolonged hospitalization [6]. Clinical circumstances such as advanced age, dependence on continuous anti-coagulation or anti-aggregation or concomitant disorders may, however, significantly increase the risks associated with surgery.

The basic principle of aneurysm coiling is to fill the aneurysm sac with platinum coils using a microcatheter. This prevents further blood flow into the aneurysm, so that it then thromboses, thus the aneurysm is excluded from blood circulation. Coils have some disadvantages. Precise positioning of the coils in a straight artery can be difficult, as coils with bare surfaces may not have sufficient grip on the vessel wall, which can lead to migration of the distal coils. In addition, the thrombogenicity of the coils is low, and the remaining space between coil loops allows for blood reflux even after a dense packing of coils and the aneurysm can re-grow [7]. In order to prevent this, regular angiographic control examinations (= follow-ups) are performed (e.g., 3 - 6 months and 7-

12 months after the initial intervention). In case of recanalization or re-growth, re-treatment using platinum coils, or another alternative method is required.

Neurovascular flow diverters are self-expanding, tubular stent-like implants consisting of a fine braided wire structure that are used for the endovascular treatment of extra- and intracranial aneurysms. The goal of flow diversion is to reconstruct the diseased arteries by optimally modulating the blood flow and thus exerting a disruption of the flow into and out of the aneurysm sac [8]. However, stent-assisted coiling is more suitable to treat wide-neck aneurysms.

6.2 Atherosclerotic stenosis (ICAS) treatment

The conservative approach to treat ICAS involves making lifestyle changes to address risk factors (e.g., blood pressure and LDL cholesterol), as well as using statins (cholesterol-lowering drugs) to stabilize plaque and antiplatelet medications to reduce the risk of arterio-arterial embolic ischemia. The use of dual antiplatelet therapy in the treatment of ICAS has increased. This approach involves the use of both Acetylsalicylic acid (ASA) and clopidogrel to reduce the risk of recurrent stroke. However, patients have to be tested for anti-platelet resistance beforehand and in case of insufficient response, switched to other medication, e.g., ticagrelor or prasugrel. The SAMMPRIS[a] trial demonstrated lower early recurrent stroke rates in patients receiving intensive medical management, including dual antiplatelet therapy, compared to the WASID[b] trial, in which patients were taking either ASA or warfarin. After adjusting for baseline differences, patients from the WASID trial had a significantly higher risk of the primary outcome as in the SAMMPRIS trial. This suggests that the aggressive medical management used in the SAMMPRIS trial contributed to the lower rate of stroke in the medical arm [9, 10]. However, conservative treatment relies on patient adherence to lifestyle modifications and medication regimens. The high-risk subgroup of patients with 70% - 99% stenosis who do not respond to medical management may not benefit from the conservative treatment and are at a higher risk [10, 11].

The endovascular approach consists of the use of balloon- and stent angioplasty techniques.

Balloon angioplasty involves inserting a deflated balloon into the narrowed artery and inflating it to widen the vessel and improve blood flow. While balloon angioplasty is a commonly used treatment for atherosclerotic stenosis, it does have some limitations, such as immediate elastic recoil of the artery, dissection, acute vessel closure, residual stenosis after the procedure, and high restenosis rates [11]. Reports of studies which compared balloon angioplasty with stent placement indicate that patients who undergo balloon angioplasty alone may have higher rates of restenosis and potentially worse clinical outcomes after 2 years compared to patients who receive stents. However, it is important to note that these studies had limitations, including their retrospective design and low statistical power to detect significant differences between the stented and angioplasty groups.

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[a] The SAMMPRIS (Stenting vs. Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis) was a randomized, multi-centre trial which evaluated stents compared with medical therapy for treatment of intracranial stenosis among patients who had a stroke or transient ischemic attack (TIA) within the previous 30 days. The enrollment was stopped because the stroke or death rate was found to be higher in the stenting group compared to medical-management group.

[b] The Warfarin–Aspirin Symptomatic Intracranial Disease (WASID) Trial was a randomized controlled trial that compared warfarin and aspirin for preventing the primary endpoint of ischemic stroke, brain hemorrhage, and vascular death in patients with stenosis (50 to 99%) of a major intracranial artery. The trial was stopped prematurely because warfarin was associated with significantly higher rates of adverse events and provided no benefit over aspirin.

Balloon angioplasty can be performed alone or in combination with the placement of a stent to stabilize the widened artery.

This approach involves predilation of the stenosed vessel with an undersized balloon to prevent vascular injuries like dissections and ruptures. The goal is not to fully restore the original lumen, but rather to achieve adequate blood flow [9]. Some interventionalists prefer using self-expanding stents in the M1 segment of the middle cerebral artery due to specific anatomical conditions. On the other hand, balloon-mounted stents are more commonly used in the posterior circulation, specifically in the V4 segment of the vertebral artery, the basilar artery, and the intracranial section of the carotid artery [9]. ICAS that only becomes evident during the mechanical thrombectomy is one risk factor that increases the occurrence of re-occlusion of the vessel shortly after the thrombectomy (36.9% instead of 2.7% without ICAS) [12]. For this specific condition the physician needs to decide individually on patient level whether a treatment with additional medication, a balloon or a rescue stent is the most promising treatment, as each treatment has a different risk profile.

7 Suggested profile and training for users

The devices may only be used in a (neuro-) radiological clinic by specialized, appropriately trained physicians who are experienced in the use of implants for the treatment of diseased arteries. Participation in a product training course from phenox GmbH is recommended for the use of the products.

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

The standards defined as the most important applicable standards are listed below:

- EN ISO 14630 *Non-active surgical implants - General requirements* (Status: 2024)
- EN ISO 25539-2 *Cardiovascular implants - Endovascular implants - Part 2* (Status: 2020)
- ISO 17327-1 *Non-active surgical implants - Implant coating - Part 1* (Status: 2018)

Each individual requirement point of the respective standard is evaluated in the Technical Documentation. Applicable points are adopted as requirements in the Technical Documentation. If a requirement point is not applicable, this is justified accordingly.

9 Revision history

Table 7: Revision history

SSCP Revision number	Date issued	History	Revision validated by the Notified Body
Rev. A	n/a	Initial set-up of the document	☐Yes Language of validation: English ☒No

SSCP Revision number	Date issued	History	Revision validated by the Notified Body
Rev. B	04.08.2024	Adaption of Rev. A draft to include technical complications to align with technical documentation.	☒Yes Language of validation: English ☐No
Rev. C	n/a	Adaption of the SSCP to align with updated Clinical Evaluation.	☐Yes Language of validation: English ☒No
Rev. D	Date of release of the Notified Body: 03.03.2026	Adaption of the SSCP to align with updated Clinical Evaluation in July 2025.	☒Yes Language of validation: English ☐No

Summary of Safety and Clinical Performance (SSCP)

for the class III medical device group

Neurovascular Stent

consisting of

pEGASUS and pEGASUS HPC

Patients and lay persons

Summary of safety and clinical performance for patients and lay persons

A summary of the safety and clinical performance of the medical device group Neurovascular Stent, intended for patients and lay persons, is given in this section.

Document number: SSCP-0005
Document revision: Rev. D
Date of issue: Issue date according to the Notified Body 03.03.2026

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 medical device group Neurovascular Stent. The information presented below is intended for patients or lay persons. 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 (IFU) to provide information on the safe use of the device.

Terms, abbreviations and definitions

Term	Definition
Adequate occlusion	Complete exclusion or near complete exclusion of the aneurysm from the blood circulation.
Aneurysm	Bulge or weakening in the wall of a blood vessel.
Angiographic techniques	Imaging, radiological procedure in which the vessels are filled with contrast medium and made visible with the help of X-rays, magnetic resonance tomography or computer tomography.
Anticoagulation	Medical treatment used to prevent blood clots from forming or to break up existing blood clots in the body with the help of blood thinners.
Artery	Blood vessel that takes blood away from the heart to other parts of the body.
Atherosclerotic stenosis	Narrowing or blocking of the arteries within the brain due to the buildup of plaque. Plaque is formed by the accumulation of cholesterol, fat, calcium, and other substances in the walls of arteries.
Balloon angioplasty	Medical procedure used to treat vessels that become narrow or blocked. During the procedure, a balloon is inflated temporarily in the target vessel to widen it and improve the blood flow.
Basic UDI-DI	*Basic Unique Device Identification - Device Identifier* Used to identify and register medical devices on the European Union market.
Cervical	Cervical refers to the area of the body related to the neck or the cervix.
Clinical morbidity	The state of suffering from a disease or medical condition.
Coil	Thin wires mostly made of platinum which are designed to pack tightly into the aneurysm, promoting blood clotting and preventing aneurysm rupture.
Comorbidity	Presence of two or more diseases.
Complete aneurysm occlusion	Complete exclusion of the aneurysm from the blood flow.
Contraindication	Reason against the treatment.
Craniotomy	Surgical operation in which a bone flap is temporarily removed from the skull to access the brain.
DAPT	*Dual Antiplatelet Therapy*

Term	Definition
	Usage of two platelet function inhibitors which are medications that reduce the ability of platelets, a type of blood cell involved in clotting which stick together and form blood clots.
Endovascular	Within the blood vessels
ESO	European Stroke Organisation
Dissection	Splitting of the wall layers of an artery.
Femoral artery	Large artery located in the thigh region of the body. It is one of the major arteries supplying blood to the lower extremities.
Fusiform aneurysm	A „false“ aneurysm which can occur after a vessel injury. Pseudoaneurysms typically occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury.
FSCA	Feld Safety Corrective Actions
FSN	Field Safety Notices
Hemorrhagic	Bleeding
Hemorrhagic stroke	Type of stroke that occurs when there is bleeding in the brain. It is usually caused by the rupture or leakage of a blood vessel in the brain.
HPC	*Hydrophilic Polymer Coating* Coating that imitates the natural lining of the inner vessel wall to prevent the platelets from recognizing the implant as a foreign body and thereby initially reduce the risk of thrombus formation.
ICAS	*intracranial atherosclerotic stenosis* Medical condition characterized by the buildup of plaque within the arteries supplying blood to the brain.
IFU	*Instructions For Use* Information provided by the manufacturer to inform about the intended purpose, correct use, and any precautions
Imaging technique	Technique used to clearly visualize blood vessels e.g., Digital Subtraction Angiography – DSA.
Indication	Reason for treatment
Infarction	Condition in which an area of tissue or organ undergoes cell death due to a lack of blood supply.
Intended purpose	The use for which a device is intended.
Intracranial	Within the skull
Interventional neuroradiology	Medical subspecialty that uses minimally invasive techniques to diagnose and treat diseases of the brain, spine, and central nervous system.
Ischemic	Inadequate blood supply to a particular organ or tissue.
Ischemic stroke	Type of stroke that occurs when a blood vessel supplying oxygen and nutrients to the brain becomes blocked or narrowed, leading to decreased blood flow to a specific region of the brain.
Microcatheter	Thin flexible tube that is used in medical procedures to deliver medications, contrast agents, or other fluids and medical devices, such as neurovascular stents to specific locations in the body.
(Micro) Guidewire	(Micro) Guidewires are thin flexible wires which are used to navigate the microcatheter (= thin flexible tube) and thus the respective device to the target lesion.
MRI	*Magnetic Resonance Imaging* Non-invasive medical imaging test that produces detailed images of almost every internal structure in the human body, including blood vessels.
mRS score	*modified Rankin Scale* Score that is used to assess your/the patient's condition and indicates the degree of functional independence.

Term	Definition
Neck remnant	Near complete exclusion; refers to the portion of the aneurysm that remains open after treatment.
Neurological deficits	Abnormalities or impairments in the structure or function of the nervous system, which includes the brain, spinal cord, and nerves.
NIHSS	*National Institutes of Health Stroke Scale* Scale that assesses stroke-related neurologic deficits
Occlusion rate	Complete exclusion or near complete exclusion of the aneurysm from the blood circulation.
Platelet	Small, colorless blood cell, also known as thrombocyte, that is essential for blood clotting.
Platelet function inhibitor	Medication that reduces the ability of platelets, a type of blood cell involved in clotting which stick together and form blood clots.
PMCF	*Post-Market Clinical Follow-Up* Manufacturer collects and evaluates clinical data from the use of the approved device.
Pseudoaneurysm	A „false“ aneurysm which involves a dilatation of the arterial wall which is caused by a disruption in the arterial wall. Pseudoaneurysms occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury.
Residual	Remaining
Restenosis	Narrowing that recurs
Rupture	Sudden breaking or bursting
SAH	*Subarachnoid hemorrhage* Bleeding in the space that surrounds the brain.
SAPT	*Single Antiplatelet Therapy* Usage of one platelet function inhibitor which is a medication that reduces the ability of platelets, a type of blood cell involved in clotting which stick together and form blood clots.
SSCP	*Summary of Safety and Clinical Performance* Provides public access to an updated summary of the main aspects of the safety and clinical performance of the medical device group.
Stenosis/stenosed	Narrowing of an artery/vessel
Stroke	Medical condition that occurs when the blood supply to a part of the brain is interrupted or reduced, depriving the brain tissue of oxygen and nutrients. This can cause brain cells to die within minutes.
Thrombocyte	Small, colorless blood cell, also known as platelet that is essential for blood clotting.
Thrombogenicity	Ability of a substance or material to promote the formation of blood clots.
Thrombus	Blood clot
Thrombosis	Formation of a blood clot (thrombus) within a blood vessel, obstructing the flow of blood through that vessel.
Vasospasm	Sudden constriction- usually- of an arterial vessel.

1 Device identification and general information

Device trade name

The medical device group Neurovascular Stent consists of the variants pEGASUS (bare) and pEGASUS HPC (coated) (refer to Table 8). The device version with the suffix “HPC” carry a hydrophilic polymer coating.
For more details on the HPC coating, please refer to chapter Device description.

In this document, the term pEGASUS (HPC) is used for the description of both device variants.

Table 8: Classification of the medical device group Neurovascular Stent.

Medical device group	Neurovascular Stent	
Basic UDI-DI	426012378NeuroStentTE	
Product family	pEGASUS (HPC)	
Design variant	pEGASUS	pEGASUS HPC
Trade name	pEGASUS Stent System	pEGASUS HPC Stent System
Structure of REF*	PEGASUS-XXX-XX	PEGASUS-XXX-XX-HPC

*1: XXX - Max. insertion vessel-Ø; 2: XX – Length in max. insertion vessel -Ø; HPC: Coating

Manufacturer; name and address

phenox GmbH
Lise-Meitner-Allee 31
44801 Bochum
Germany
Tel.: +49 (0)234 36 919-0
Fax: +49 (0)234 36 919-19
E-Mail: info@wallabyphenox.com
Website: www.phenox.net

Basic UDI-DI (Device identification number)

The device identification number, also known as "Basic UDI-DI" (Basic Unique Device Identification - Device Identifier), is used to identify and register medical devices on the European Union market. The Basic UDI-DI for the medical device group Neurovascular Stent is **426012378NeuroStentTE**.

Year when the device was first CE-marked

Table 9: Certification dates and CE-certificate number.

Regulatory background	Product variant	First CE-certification	Certificate number
MDD	**pEGASUS HPC**	22.02.2021	549256 MRA[d]
	pEGASUS		
MDR[e]	**pEGASUS HPC**	18.09.2024	31625664 MDR2017P
	pEGASUS		

Intended purpose

The medical device pEGASUS (HPC) Stent System is a self-expanding, tubular vascular implant and allows the endovascular (= *within the blood vessels*) reconstruction of diseased arteries (= *blood vessel that takes blood*

[c] Medical Device Directive (93/42/EEC). The MDD was the most important regulatory instrument for demonstrating the safety and medical-technical performance of medical devices in the European Economic Area until the Medical Device Regulation was introduced (valid until 26.05.2021)

[d] Mutual Recognition Agreement according to Medical Device Directive

[e] Medical Device Regulation was introduced on 27.05.2021

away from the heart to other parts of the body) in the cervical (= *area of the body related to the neck or the cervix*) and intracranial (= *within the skull*) course.

The implants of the design variant pEGASUS HPC also have a hydrophilic polymer coating, which initially reduces the adhesion of thrombocytes (= *small, colorless blood cell that is essential for blood clotting*) and thus reduces the risk of thrombus (= *blood clot*) formation (based on *in vitro*[f] data [1]).

Indications and intended patient groups

As described in the Instructions for Use (IFU), the pEGASUS (HPC) devices are designed for the endovascular (= *medical procedure or technique that is performed inside a blood vessel or other hollow structure in the body*) treatment of vascular diseases such as:

- saccular and fusiform aneurysms (= *bulge or weakening in the wall of a blood vessel*) and pseudoaneurysms (= *a „false" aneurysm which can occur after a vessel injury. Pseudoaneurysms typically occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury*) in combination with coils (= *thin wires mostly made of platinum)* and
- atherosclerotic vascular stenosis of intracranial arteries (= condition characterized by the buildup of plaque within the arteries supplying blood to the brain).

Patients are not eligible for treatment when they have one of the aspects listed in the "Contraindications" section. This device is only intended for adult persons 16 years and over.

Contraindications

Patients with an inadequate *(=insufficient*) antiplatelet therapy or insufficient anticoagulant treatment according to standard medical practice before, during, and after the treatment.
Angiography *(=imaging of your brain)* demonstrates the anatomic conditions are not appropriate for endovascular (=*within the artery*) treatment, such as severe vessel tortuosity or severe stenosis *(=narrowing of the artery)*.

In case you have questions regarding the indications (= *reason for treatment*) or contraindications (= *reason against the treatment*), please refer to your/the treating doctor.

2 Device description

Device description and material/substances in contact with patient tissues

pEGASUS (HPC) is an implant (5) which is placed in the artery that is to be treated with the help of a delivery system. The delivery system carries markers at both ends (3,6) which allows the doctor to determine the position of the device. In addition, the device has markers (4) which are made of platinum at both ends so that it can be seen on X-rays which facilitates the placement of the device.

The implant is stored in a sheath and then put into a thin flexible tube called a microcatheter. A "Fluorosafe Marker" (2) on the implant helps to identify the position to which the implant can be advanced inside the microcatheter without leaving the microcatheter. The implant self-expands as it leaves the microcatheter and

[f] Organic processes that take place outside a living organism, e.g., in a test tube, as opposed to those that take place in the living organism (*in vivo*).

cannot be withdrawn. When the microcatheter is withdrawn, the implant is completely released and thus detached from the delivery system.

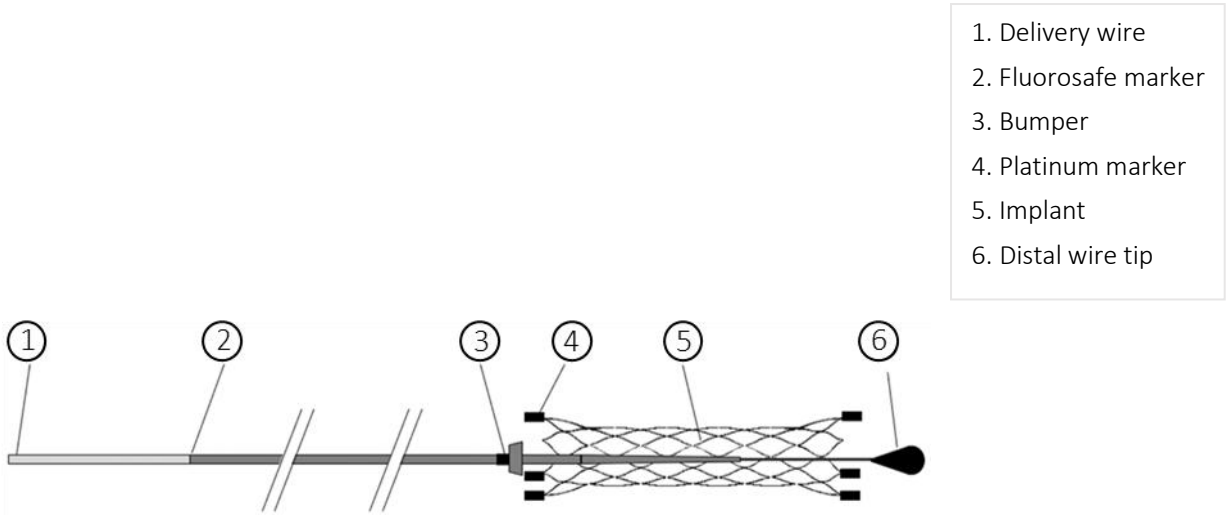

Figure 3: Delivery system and detached pEGASUS (HPC) implant.

The stents are also available with a Hydrophilic Polymer Coating (HPC). The HPC coating is designed to imitate the natural lining of the inner vessel wall, the so-called "glycocalyx" layer. *In-vitro*[g] test results [1] have shown that the HPC coating can prevent the platelets, which are small cells in the blood that help with blood clotting, from recognizing the implant as a foreign body and thereby initially reduce the risk of thrombus (= *blood clot*) formation. If justified by individual circumstances, the initially reduced thrombogenicity (= *ability of a substance or material to promote the formation of blood clots*) may allow the implantation with only one single antiplatelet medication [2].

In case you have questions regarding this topic, please refer to your/the treating doctor.

Materials that come in contact with the central circulatory system of you/the patient are listed in Table 10.

Table 10: Materials that come in contact with you/patient during the intervention.

Materials that come in contact with patient during the intervention	
Implant (Long term contact)	**Insertion wire (Short term contact)**
- Nickel-Titanium Alloy	- Nickel-Titanium Alloy
- Platinum-Iridium Alloy	- Platinum-Iridium Alloy
- If applicable: HPC (Hydrophilic Polymer Coating)	- Stainless Steel
	- Polytetrafluoroethylene (PTFE)

In case you have questions regarding the device design or the materials that come in contact with you/the patient, please refer to your/the treating doctor.

[g] Organic processes that take place outside a living organism, e.g., in a test tube, as opposed to those that take place in the living organism (*in vivo*).

Information about medicinal substances in the device

The pEGASUS (HPC) devices do not contain any medical substances.

Description of how the device is achieving its intended mode of action

The products of the medical device group Neurovascular Stent (= pEGASUS (HPC)) are intended to treat brain aneurysms in intracranial (= *within the skull*) arteries (= *blood vessel that takes blood away from the heart to other parts of the body*). An aneurysm is a dilatation or a bulge in a blood vessel which is caused by weakness in the vessel wall. The most common place for their occurrence is arteries, which are vessels that transport blood away from the heart to the rest of the body. In such arteries the blood pressure can cause small areas to bulge outwards like a balloon. These bulges carry a risk of rupture and eventually causing bleeding within the brain. Different aneurysm types, such as "saccular", "fusiform" and "pseudoaneurysms" can be treated with pEGASUS (HPC). Unlike a saccular aneurysm, which has a round sac-like bulge, a fusiform aneurysm involves more a uniform dilatation of the blood vessel in a ballooning shape. A pseudoaneurysm is also known as a false aneurysm. An aneurysm involves a dilatation of the arterial wall, however a pseudoaneurysm is caused by a disruption in the arterial wall. Pseudoaneurysms occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury.

The so-called stent-assisted coiling is used to treat aneurysms. During the procedure, a suitable microcatheter *(= thin flexible tube)* is used to deliver the stent as well as the coils at the target position. The microcatheter is inserted into the femoral artery *(= large artery located in the thigh region of the body. It is one of the major arteries supplying blood to the lower extremities; refer to Figure 4)* and is advanced to the location of the brain aneurysm. Once in position, the stent is advanced through the microcatheter and positioned across the neck of the aneurysm to provide support and prevent coil *(= thin wires mostly made of platinum which are designed to pack tightly into the aneurysm, promoting blood clotting and preventing aneurysm rupture)* prolapse or migration. Coils are then advanced through the same or a further microcatheter and placed within the aneurysm to fill it. These coils support blood clotting in the aneurysmal space so that the aneurysm can occlude. Coils can also be inserted into the aneurysm in the first step and then the stent can be implanted in the second step.

In addition, pEGASUS (HPC) is indicated for the treatment of intracranial atherosclerotic stenosis (ICAS), also known as intracranial atherosclerosis. This condition refers to the narrowing or blocking of the arteries within the brain due to the buildup of atherosclerotic plaques. Plaque is formed by the accumulation of cholesterol, fat, calcium, and other substances in the walls of arteries. When intracranial atherosclerosis occurs, the arteries supplying blood to the brain become narrowed or blocked, reducing blood flow to the affected areas which can result in various neurological symptoms and even in a stroke *(= medical condition that occurs when the blood supply to a part of the brain is interrupted or reduced, depriving the brain tissue of oxygen and nutrients)*. In such cases, a neurovascular stent, such as the pEGASUS (HPC) stent is used to widen the narrowed artery. This procedure is supported by balloon angioplasty, in which a small balloon is inflated temporarily in a first step to widen the diseased artery. Afterwards a stent, like pEGASUS (HPC), is implanted in the widened artery to support the artery wall and stabilize it in the dilated form. Intracranial atherosclerotic stenosis (ICAS) that only becomes evident during the mechanical thrombectomy (=*treatment in which a blood clot is removed from vessels*) is one risk factor that increases the occurrence of re-occlusion of the vessel shortly after the thrombectomy (36.9% instead of 2.7% without ICAS) [12]. For this specific condition the physician needs to decide individually on patient level whether a treatment with additional medication, a balloon or a rescue stent, e.g., pEGASUS (HPC), is the most promising treatment, as each treatment has a different risk profile.

In case you have questions regarding the intended mode of action of the pEGASUS (HPC) devices, please refer to your/the treating doctor.

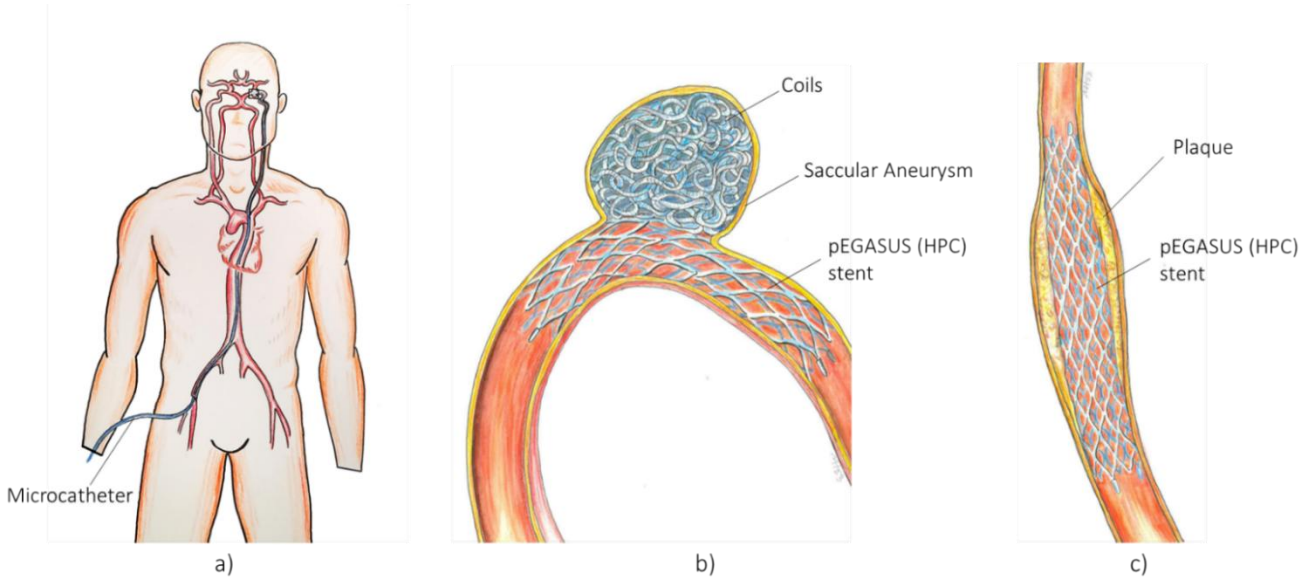

Figure 4: a) Route of the microcatheter (= *thin flexible tube*) to the target lesion through the right femoral artery. b) Placement of pEGASUS (HPC) across a saccular aneurysm. c) Placement of pEGASUS (HPC) in a stenosed (= *narrowed*) artery. Drawing by Mark Hobert (phenox GmbH) and inspired by Brisman *et al.* (2006)[13].

Description of accessories and related products

pEGASUS (HPC) is compatible with equipment commonly used in interventional neuroradiology *(= medical subspecialty that uses minimally invasive techniques to diagnose and treat diseases of the brain, spine, and central nervous system)*. This includes products for minimally invasive implantation of the device, such as microcatheters. A short description of the related products is given below. pEGASUS (HPC) has no accessories.

Microcatheter

The pEGASUS (HPC) devices are advanced to the target lesion through thin flexible tubes, the so-called microcatheters.

(Micro) Guidewire

(Micro) Guidewires are thin flexible wires which are used to navigate the microcatheter and thus the respective device to the target lesion.

Coils

Coils are used in combination with the pEGASUS (HPC) devices to support occlusion of aneurysms which means that the aneurysm is excluded of from the blood flow.

Implant card

Every patient to be treated with a pEGASUS (HPC) device is supplied with an implant card. This is included in the product box and is to be filled out by your/the treating doctor and handed over to you/the patient after the treatment. **You/The patient will be instructed to always carry this implant card with him/her**. The implant card includes a scannable QR-Code, the patient's identifying information, as well as the direct website domain that contains this document, i.e., the Summary of Safety and Clinical Performance (SSCP). In addition to the patient's first and last name, the implant card contains all important information about the implant itself, the manufacturer of the device, as well as the date of implantation and the responsible medical institution and healthcare professional.

3 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the treatment with the pEGASUS (HPC) device or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed

This section describes how risks can be reduced and the possible treatment options.
Before a treatment with the pEGASUS (HPC) devices, the correct device size has to be selected by the doctor. Also, the selected device must be checked for damage before use. In general, the devices are not allowed to be used if these are deformed or damaged, as function cannot be assured otherwise.
pEGASUS (HPC) devices are in contact with blood, sodium chloride solution, X-ray contrast media, foreign products / materials (e.g., coils= thin wires), blood thinning agents. pEGASUS (HPC) devices do not contain ingredients which may be considered as medical substances.
The implantation of pEGASUS (HPC) requires the administration of medication which inhibits the platelet *(= blood cells which initiate blood clotting)* function. Usually, two platelet function inhibitors ("dual antiplatelet therapy"= DAPT; *usage of two platelet function inhibitors which are medications that reduce the ability of platelets, a type of blood cell involved in clotting which stick together and form blood clots)* are given in appropriate doses. If justified by individual circumstances, the HPC devices may allow the implantation under single antiplatelet medication (SAPT) [2]. **If you have any questions regarding the agents, please consult your/the doctor.** The effectiveness of the given medication is to be verified by an appropriate test. Implantation of pEGASUS (HPC) devices without effective platelet function inhibition can lead to severe complications. **Please contact your/the doctor, if you have questions regarding this topic.**
Some of the important complications that can occur during or after a treatment are explained in the following section.
Stroke *(= medical condition that occurs when the blood supply to a part of the brain is interrupted or reduced, depriving the brain tissue of oxygen and nutrients)* may occur as a result of pEGASUS (HPC) implantation. There are two types of strokes, ischemic stroke and hemorrhagic stroke. Ischemic stroke is caused by a sudden reduction in blood flow to the brain, known as ischemia resulting in an inadequate supply of oxygen and glucose. The reduced blood flow is usually caused by a stenosis *(= narrowing)* or thrombosis *(= formation of a blood clot within a blood vessel)* of the arteries supplying the brain. Hemorrhagic stroke is the most feared complication. In this case, intracerebral hemorrhage *(= bleeding into the brain tissue)* or subarachnoid hemorrhage *(= bleeding between the inner and middle layers of the brain)* occur, e.g., due to a vessel rupture *(= sudden breaking or bursting*) or a vessel injury. Such bleedings can lead to a so-called "vasospasm" *(= sudden constriction - usually - of an arterial vessel).* As a result of the reduction in blood flow to the brain due to sudden constriction, the brain tissue is not receiving enough oxygen and can die, as in the case of an ischemic stroke. If a vasospasm occurs, it can be treated with medications that promote widening of the vessel, balloon angioplasty *(= widening of the affected artery with temporary inflation of a balloon)* aiming at widening the vessel, or a combination of these techniques. It is the doctor's decision how to proceed and depends on different factors e.g., condition of you/the patient. **Please contact your/the doctor if you have questions regarding this topic.**
A so-called "false aneurysm" or "pseudoaneurysm" can occur after a dissection *(= splitting of the wall layers of an artery)* or after vessel injury. Pseudoaneurysms typically occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury.

Please note that after pEGASUS (HPC) device implantation you/the patient will have control visits. During these visits, your/the doctor will check your/the patient's health condition and control the position of the pEGASUS (HPC) device and the status of the aneurysm via imaging techniques *(= technique used to clearly visualize blood*

vessels e.g., Digital Subtraction Angiography - DSA). In some cases, the lesion has to be retreated because of aneurysm regrowth/recurrence or restenosis (= *narrowing that recurs*). In this case it is the doctor's decision how to proceed. **Please contact your/the doctor, if you have questions regarding this topic.**

Residual risks and undesirable effects

The following terms are used in Table 11.

- **Air Embolism/ Embolism** = blockage of a blood vessel by air, foreign or body-own substances that have entered the bloodstream.
- **Coil herniation / Coil protrusion =** displacement or movement of the coiling material used to fill an aneurysm.
- **Cerebral hyperperfusion syndrome =** condition characterized by excessive blood flow and increased pressure in the brain. It occurs when there is an abrupt increase in cerebral (=*brain*) blood flow, typically following a surgical procedure or a blockage in the blood vessels that supply the brain.
- **Dissection** = tear or rupture in the inner lining of an artery, leading to the separation of the layers of the arterial wall.
- **Encephalopathy** = encephalopathy is a broad term used to describe a wide range of brain disorders or diseases that affect brain function. It is characterized by changes in brain structure and/or function leading to various neurological symptoms.
- **Extravasation** = leakage or escape of a fluid, such as blood, medication or contrast media, from its intended location into the surrounding tissues.
- **Hemorrhage** = bleeding, typically occurring from damaged blood vessels.
- **Hematoma** = localized bleeding outside of blood vessels, due to either disease or trauma including injury or surgery
- **Hydrocephalus** = accumulation of cerebrospinal fluid (CSF) in the brain. CSF is a clear fluid that surrounds and cushions the brain and spinal cord.
- **Ischemia =** inadequate blood supply to a particular organ or tissue, resulting in a decrease in oxygen and nutrient supply. It is commonly caused by a blockage or narrowing of the blood vessels supplying the affected area.
- **Perforation** = an injury to a vessel/a hole in a vessel or artery
- **Pseudoaneurysm** = a "false" aneurysm, which can occur after a dissection (= *splitting of the wall layers of an artery*) or after vessel injury. Pseudoaneurysms typically occur because of trauma, such as a puncture or rupture of an artery during a medical procedure or an injury.
- **Recanalization =** phenomenon where an aneurysm, which was previously treated or considered stable, redevelops or regrows blood flow within it.
- **Rupture** = tearing or bursting of a blood vessel or aneurysm.
- **Space-occupying infarction** = a type of stroke (= *forming of blood clots*) that develops extensive and acute swelling of the brain. This leads to the squeezing to adjacent and other vital areas of the brain to its space-occupying effect. If left untreated, it can lead to death.
- **Stenosis/ In-stent stenosis =** narrowing of a blood vessel, usually due to the buildup of plaque or the formation of scar tissue. In-stent stenosis is a condition in which a previously placed stent within a blood vessel becomes narrowed or blocked.
- **Thrombosis/ In-stent thrombosis** = complete or partial occlusion of a blood vessel by blood clot (= thrombus). A thrombosis within a stent is called in-stent thrombosis.
- **Vasospasm** = sudden constriction - usually - of an arterial vessel
- **Friction** during application of the product = resistance when pushing the device through the catheter

- **Fracture** of implant and/or delivery system before or during the intervention = breakage of the device or parts of the system
- **Inadequate size/shape of the implant** = too short device for a sufficient coverage of the aneurysm or too big device for a vessel
- **Unintentional release of the implant at an unplanned localization** = implantation of the device at a different part of the vessel.
- **Detachment or deployment** problems = Problems occurring during pushing the device out of the catheter, including the correct opening of the device in the vessel
- **Incomplete opening of the implant** = The device does not open to the full extent.
- **Separation failure** = problems occurring during separating the stent and the microcatheter or the part that pushes the stent out of the microcatheter.
- **Migration of implant** = Moving of the device in the vessel after the implantation.
- **Stent-coil combination issues** = Problems like coils (= thin wires, mostly made of platinum) hanging into the vessel or the coiling process being difficult through the stent.

Relevant risks and undesirable effects related to the use of neurovascular stents or the procedure, and their probability of occurrence are listed in Table 11. These numbers were derived from state-of-the-art (SOTA) and from own clinical data for pEGASUS (HPC).

Table 11: Residual risks and undesirable effects of the use of neurovascular stents or the procedure.

Complications/Risks/Side effects	Clinical data of pEGASUS (HPC) (%)
Air embolism	Not specifically reported
Allergic reaction	0.42% (not to our device but the contrast media; PMCF-data)
Coil herniation/ Coil protrusion	0% ([3] & [4] - 3.80%/2.95% (PMCF-data: 9 cases but 2 were reversible)
Cerebral hyperperfusion syndrome	Not specifically reported
Death	3.38% (PMCF-data) - 8.3%*[3]
Dissection	0% [4] – 8.1% [5]
Emboli	0.42% (PMCF-data) – 4.9% [5]
Encephalopathy	0.42% (PMCF-data)
Extravasation	0.42% (PMCF-data) – 2.7% [5]
Hemorrhage/ Hemorrhagic complication	0% [4] - 1.26% (PMCF-data)
Hematoma	Not specifically reported
Hydrocephalus	Not specifically reported
Infection	Not specifically reported
In-stent stenosis	0.84% (PMCF-data) – 11.1% [3]
Intimal hyperplasia	Not specifically reported
Ischemia/ischemic complications	1.9% [4] – 4.64% (PMCF-data)
Neurological deficit including the consequences of a stroke	5.06% (PMCF-data)
Occlusion	Not specifically reported

Complications/Risks/Side effects	Clinical data of pEGASUS (HPC) (%)
Perforation	0% [3, 4]
Persistent vegetative state	0.84% (PMCF-data)
Pseudoaneurysm	0.42% (PMCF-data)
Recanalization (Aneurysm treatment)	Not specifically reported
Restenosis/Recurrent ischemic or hemorrhagic stroke (Stenosis treatment)	Not specifically reported
Retreatment (Aneurysm treatment)	Not specifically reported
Rupture	Not specifically reported
Space-occupying infarction	2.95% (PMCF-data)
Stent thrombosis/In-stent stenosis	1.9% [4] – 8.3% [3]
Stroke (ischemic or hemorrhagic)	4.64% (PMCF-data) – 8.3% [3]
Thrombosis/ Thromboembolic complications	1.69% (PMCF-data)
Vasospasm	0.84% (PMCF-data)
Vessel stenosis	Not specifically reported
Technical Complications	**Clinical data of pEGASUS (HPC) (%)**
Friction during application of the product	0.2% (Complaints) – 3.0% (PMCF-data)
Fracture of implant and/or delivery system before or during the intervention	Not reported in own PMCF-data
Inadequate size/shape of the implant	0.5% (PMCF-data)
Unintentional release of the implant at an unplanned localization	2.5% (PMCF-data)
Detachment or deployment problems	0.1% (Complaints) – 3.85% [4]
Incomplete opening of the implant	Not reported in own PMCF-data
Separation failure	0.1% (Complaints)
Migration of implant	Not reported in PMCF clinical data
Stent-coil combination issues	3.8% (PMCF-data)

*1 patient died (1/12; 8.3%) due to pre-existing health condition [emergency case]; not procedure-related

Warnings and precautions

Concomitant medication

The antiplatelet medication is also known as "blood thinners" in everyday language. Non-compliance to the antiplatelet medication can lead to occlusion of the arteries followed by stroke. A treatment with the pEGASUS (HPC) devices is always accompanied with the antiplatelet medications as they prevent from forming blood clots in the arteries. Blood clots can block the arteries and affect the blood supply leading to damage of the tissue supplied by that artery. **If you have any questions regarding the agents, please consult your doctor.**

Precautions

As per the Instructions For Use (IFU), the pEGASUS (HPC) devices are suitable for magnetic resonance imaging *(= MRI; non-invasive medical imaging test that produces detailed images of almost every internal structure in the human body, including blood vessels)*, as shown by non-clinical tests. **In case you have questions regarding this topic, please refer to your doctor/the treating doctor.**

Control visits (= follow-up visits)

To ensure your health condition and to check the proper functioning of the implanted pEGASUS (HPC) device, control visits are performed after the treatment. Through these control visits, possible undesirable effects can be detected and treated. Furthermore, the progress and success of the treatment can be determined. The time frame for the control visits is scheduled individually by each hospital. The visit can for example include the assessment of your nervous system (= *neurological*) via the following grading scales:

- mRS score (*modified Rankin Scale*)
    - The mRS (scale ranges from 0 - 6) is used to assess your/the patient's condition. The mRS indicates the degree of functional independence. If the mRS is evaluated before and after treatment, it can be determined whether the treatment has improved or worsened your/the patient's health condition or whether your/the patient's condition is unchanged.
- NIHSS score (*National Institutes of Health Stroke Scale*)
    - The NIHSS score is a tool to systematically assess stroke-related neurologic deficits *(= abnormalities or impairments in the structure or function of the nervous system, which includes the brain, spinal cord, and nerves).* The maximum possible score is 42 (i.e., death), with the minimum score being 0 (no stroke symptoms).

In case you have questions regarding control visits, please refer to your doctor/the treating doctor.

Summary of any field safety corrective action (FSCA including FSN)

Up until now, no safety measures had to be taken for any of the pEGASUS (HPC) devices. For none of the device variants so-called “field safety corrective actions” including “field safety notices” (abbreviations: FSCA and FSN) had to be performed. All devices are still being used by the doctors and none of the devices was retrieved from the market due to lack of safety.

4 Summary of Clinical Evaluation and post-market clinical follow-up

The following sections explain how the clinical safety and performance of the pEGASUS (HPC) devices are tracked and determined. Furthermore, the basis on which the clinical safety and performance of the pEGASUS (HPC) devices is established, is described.

Clinical background of the device

Neurovascular stents have been in the market for over 20 years with a strong clinical background. The design of pEGASUS (HPC) and the clinical use is comparable to other stents that have been on the market since several years. The design of the devices is simple with no changes made since the initial launch of pEGASUS (HPC) in 2021. Neither field safety corrective actions nor field safety notices with a reported harm to the patient were reported since the launch of pEGASUS (HPC).

In case you have questions regarding the products or the treatment itself, please refer to your doctor/the doctor.

The clinical evidence for the CE-marking

Both variants have a CE-certification under the “Medical Device Directive” (MDD) since 22.02.2021 (certification number: 549256 MRA) and “Medical Device Regulation” (MDR) since 18.09.2024 (certification number: 31625664 MDR2017P).

Since 26th May 2021, the so-called “Medical Device Regulation” (MDR) is in place. No clinical study was conducted before the MDR-certification of the pEGASUS (HPC) devices, as sufficient clinical data was generated with the MDD-certified devices (so-called: "legacy devices"). The data demonstrate that the devices are safe and effective for the treatment of intracranial aneurysms as well as intracranial atherosclerotic stenosis.

Safety

The European Stroke Organisation (ESO) guidelines describe an occurrence rate of unruptured aneurysms of 3% of the population [14]. Subarachnoid hemorrhage is a subset of stroke with a particularly high death and comorbidity *(= presence of two or more diseases)* that can occur as a consequence of a ruptured aneurysm [15]. Affecting 9 out of 100 000 patients with a death rate of 50-60%, ruptured aneurysms account for 85% of SAH cases [16] [17]. Overall, SAH affects 1% to 7% of all strokes [18].

The risk of rupture for untreated aneurysms ranges from 0.4% to 17.8%, with the highest risk occurring in the first year after detection [19]. The location, size and shape of the aneurysm as well as its direction growth are associated with the risk of rupture [20]. Additional risk factors include female sex, hypertension, smoking, excessive alcohol intake, family history of polycystic kidney disease, family history of SAH or aneurysm in ≥2 relatives and age (older than 60) [16] [18] [21]. Urgent investigation to confirm SAH is crucial to facilitate early treatment to prevent rebleeding from a ruptured aneurysms, as well as minimize disability and death [22].

Own clinical data revealed that at a first control-visit (between 3-6 months after the treatment), an adequate aneurysm occlusion rate *(= complete exclusion or near complete exclusion of the aneurysm from the blood circulation)* of 94.0% was reported.
Risks related with the use of pEGASUS (HPC), or with the procedure itself, are listed in Table 11.

It is important to note that a significant proportion of complications during the treatment remain clinically silent, especially when appropriate treatment has been performed, such as administration of appropriate medication in the case of clot formation.

Based on this benefit-risk assessment and own clinical experience reported, it can be concluded that the pEGASUS (HPC) devices are safe and effective. Clinical morbidity *(= the state of suffering from a disease or medical condition)* and death rates are within acceptable limits for all patients treated with any of the pEGASUS (HPC) device.

To ensure the safety of the pEGASUS (HPC) devices, clinical data are proactively and systematically collected and analyzed based on the indications *(= reason for treatment*), contraindications *(= reason against the treatment)* and intended purpose *(= the use for which a device is intended)*. This proactive and systematic data collection is part of the so-called “Post-Market Clinical Follow-Up” (PMCF). This includes e.g., market feedback (e.g., in case doctors have complaints regarding the handling of the product), literature analysis of phenox´ own products as well as literature and clinical data analysis regarding equivalent or similar devices and analysis of federal safety databases (e.g., from Germany: BfArM or the USA: FDA-MAUDE). Furthermore, a clinical study to evaluate the safety and efficacy of the pEGASUS stent system for the treatment of intracranial aneurysms is planned (Refer to the study database *ClinicalTrials.gov*. Identifier: NCT06158087).

5 Possible diagnostic or therapeutic alternatives

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

General description of therapeutic alternatives

For the **treatment of aneurysms**, currently the following alternative treatment options are available:

- *Observation*
  Observation consists of routine periodic control imaging and doctor visits to have a look at your/the patient's aneurysm status.

- *Medical treatment*
  Medical treatment is only possible for low risk unruptured aneurysms and includes blood pressure control, moreover smoking cessation is recommended.

- *(Micro-) Surgical clipping*
  Clipping of aneurysms requires the performance of a so-called "craniotomy" *(= surgical operation in which a bone flap is temporarily removed from the skull to access the brain)*. A small MRI *(= Magnetic resonance imaging; a medical imaging technique used to produce detailed anatomical images)* compatible clothespin-like metal clip is placed across the neck of the aneurysm to seal off the neck and, thus prevent blood from entering the aneurysm (please refer to Figure 5).

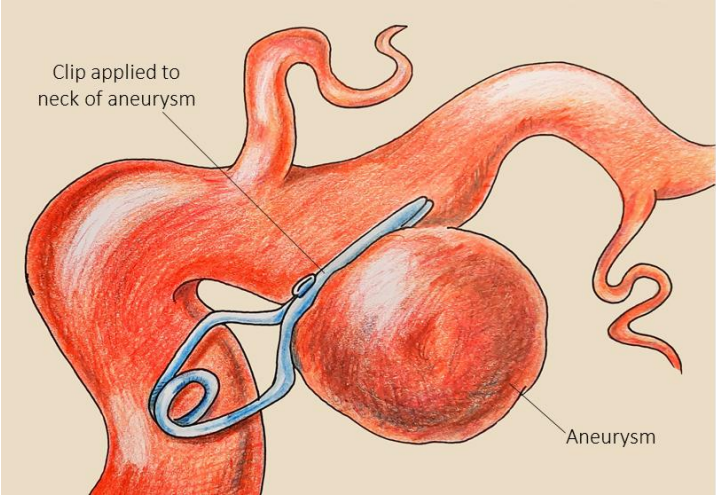

Figure 5: Application of a clip to the neck of an aneurysm (= *bulge*). Drawing by Mark Hobert (phenox) and inspired by Brisman *et al.* (2006)[13]

- *Bypass surgery*
  Aneurysm management can also be done via a bypass by performing the excisions of the lesion and recanalization of the inflow and outflow arteries, with or without grafting.

- *Coiling/ Balloon-assisted coiling*
  Coils are thin detachable platinum wires, which are packed into the aneurysm) to support blood clotting and close off the aneurysm. Therefore, with the use of angiographic techniques *(= imaging, radiological procedure in which the vessels are filled with contrast medium and made visible with the help of X-rays, magnetic resonance tomography or computer tomography)*, a microcatheter is advanced into the aneurysm.

Once the catheter reaches the aneurysm, a coil is inserted which fills the aneurysmal sac. The coil is left in place permanently. However, treatment of wide-neck aneurysms by coiling alone potentially has a higher risk of poor outcome results compared to narrow-neck aneurysms because of the movement of coils. In such aneurysms, an additional balloon is temporary inflated across the aneurysm neck to cover the neck and thus prevent the coils from falling out of the aneurysm.

Several factors must be considered to identify the best treatment method, including aneurysm location, size, shape, patient's age and medical history.

For the **treatment of intracranial atherosclerotic stenosis** (= *narrowing or blocking of the arteries within the brain due to the buildup of cholesterol, fat, calcium, and other substances in the walls of arteries; ICAS*); currently the following alternative treatment options are available:

- *Medical treatment*
  The use of dual antiplatelet therapy (DAPT) can be efficient in treating ICAS.

- *Bypass surgery*
  Bypass surgery for intracranial atherosclerosis is a surgical procedure that aims to restore blood flow to the brain by creating a new blood path avoiding the blocked or narrowed blood vessels caused by atherosclerosis.

- *Balloon angioplasty*
  Balloon angioplasty involves inserting a deflated balloon into the narrowed artery and inflating it to widen the vessel and improve blood flow. While balloon angioplasty is a commonly used treatment for atherosclerotic stenosis (ICAS), it does have some limitations, such as immediate elastic recoil of the artery, dissection, acute vessel closure, residual stenosis after the procedure, and high restenosis *(= narrowing that recurs)* rates [11].

Please contact your/the doctor if you have questions regarding alternative treatment options.

6 Suggested training for users

The pEGASUS (HPC) devices may only be used in a (neuro-) radiological hospital by specialized, appropriately trained doctors who are experienced in the use of neurovascular stents. Participation in a product training course from phenox GmbH is recommended to doctors for the use of the devices.

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