



Summary of Safety and Clinical Performance (SSCP)

for the class III medical device group

Thrombectomy Systems

consisting of

pRESET product family

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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 “Thrombectomy Systems” 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 Thrombectomy Systems.

The SSCP is not intended to provide general advice on the diagnosis or treatment of ischemic stroke nor to replace the Instructions for Use (IFU) as the primary documents provided to ensure the safe use of the medical device group Thrombectomy Systems.

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.



Summary of Safety and Clinical Performance (SSCP)

for the class III medical device group

Thrombectomy Systems

consisting of

pRESET product family

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 Thrombectomy Systems.

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 Thrombectomy Systems and other healthcare professionals.

1 Device identification and general information

1.1 Device trade name(s)

The medical device group "Thrombectomy Systems" consists of the variants pRESET STANDARD, pRESET LUX, pRESET LITE and electrolytically detachable versions (design variants with the suffix "D") (refer to Table 1).

Table 1: Medical device group "Thrombectomy systems"

Medical device group (generic name)	Thrombectomy Systems						
Product family	pRESET						
Trade name (short)	pRESET STANDARD		pRESET STANDARD D	pRESET LUX	pRESET LUX D	pRESET LITE	pRESET LITE D
Structure of the REF	PRE-X-XX	PRES-X-XX	PRE-X-XX-D	PRE-LUX-X-XX	PRE-LUX-X-XX-D	PRE-LT-X-XX	PRE-LT-X-XX-D
Available device sizes	4-20, 6-30	5-40, 6-50	4-20, 5-40, 6-30, 6-50	4-20	4-20, 5-40, 6-30, 6-50	3-20, 4-20	

1.2 Manufacturer's name and address

phenox GmbH
Lise-Meitner-Allee 31
44801 Bochum
Germany

1.3 Manufacturer's single registration number (SRN):

The SRN of phenox GmbH is **DE-MF-000006524**.

1.4 Basic-UDI-DI (Device identification number)

The Basic-UDI-DI for the medical device group Thrombectomy Systems is **426012378ThrombectomyF6**.

1.5 Medical device nomenclature description/text

According to the European Medical Device Nomenclature (MDR 2017/745, Article 26) (EMDN), the medical device group Thrombectomy Systems belongs to **C010404020402 "MECHANICAL NEUROVASCULAR THROMBECTOMY AND THROMBOASPIRATION SYSTEMS"**.

1.6 Class of device

The devices of the medical device group Thrombectomy Systems are classified as **Class III medical devices** according to Annex VIII, Rule 6 Point 3 of the Medical Device Regulation (MDR) 2017/745.

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

The certification dates and CE-certificate number according to MDD and MDR for all pRESET variants are listed in Table 2.

Table 2: Certification dates and CE-certificate number

Product variant	First CE-certification according to MDD	Certificate number according to MDD
pRESET 4-20	20.08.2011	495569 MRA
pRESET 6-30	01.06.2012	
pRESET LITE	11.11.2013	
pRESET 5-40	05.09.2019	
pRESET LUX	05.09.2019	
pRESET 6-50	18.02.2021	
Product variant	First CE-certification according to MDR	Certificate number according to MDR
Thrombectomy Systems	22.03.2024	495569 MDR2017P

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

Single identification number: 0297

2 Intended use of the device

2.1 Intended purpose

The intended purpose of the medical device group Thrombectomy Systems is treatment of acute ischemic stroke by removal of thrombi from intracranial vessels e.g., the internal carotid artery, middle cerebral artery, or basilar artery or from vessels situated distally of them, with a temporary contact duration ≤ 60 minutes.

2.2 Indication(s) and target population(s)

Indications:

The medical device group Thrombectomy Systems is designed for mechanical clot retrieval from intracranial vessels as acute ischemic stroke treatment

- for patients who are ineligible for intravenous thrombolysis or
- for patients who failed thrombolysis therapy and
- as a supplement treatment of an initiated thrombolysis therapy.

Target Population:

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

2.3 Contraindication(s) and/or limitations

The use of the medical device group Thrombectomy Systems is contraindicated in patients with

- preexisting hemorrhage in the brain tissue supplied by the target vessel,
- established infarction in the brain tissue supplied by the target vessel,
- known sensitivity to nickel-titanium,
- stenosis and/or previously implanted stent proximal to the thrombus site that may preclude safe recovery of the device,
- tortuous intracranial vessels precluding safe retraction of the device,
- angiographic evidence of carotid dissection,
- vessels with a diameter smaller than the lower limit as indicated in the IFU labeling.

3 Device description

3.1 Description of the device

The individual embodiments consist of a stent device, which is firmly connected proximally to an introducer wire.

A marker ("FLUOROSAFE MARKER") on the insertion wire identifies the position to which the device can be advanced inside the microcatheter without the device leaving the microcatheter.

Depending on the embodiment, visibility by X-ray fluoroscopy is achieved via a noble alloy coating (NAC) of the stent device and/or by X-ray markers at the proximal and distal ends of the stent device.

Depending on the design, the products are compatible with either 0.027", 0.021" or 0.017" microcatheters. The **pRESET STANDARD** and **pRESET LITE** including the versions with suffix "D" consist of a self-expanding Nitinol structure, carry one X-ray visible marker on their proximal and two on their distal end and are firmly attached to an insertion wire.

The **pRESET LUX** including the version with suffix "D" consists of a self-expanding radiopaque Nitinol structure, carries one X-ray visible marker each on its proximal and its distal end and is firmly attached to an insertion wire.

For schematic illustrations please see Figure 1 - Figure 4.

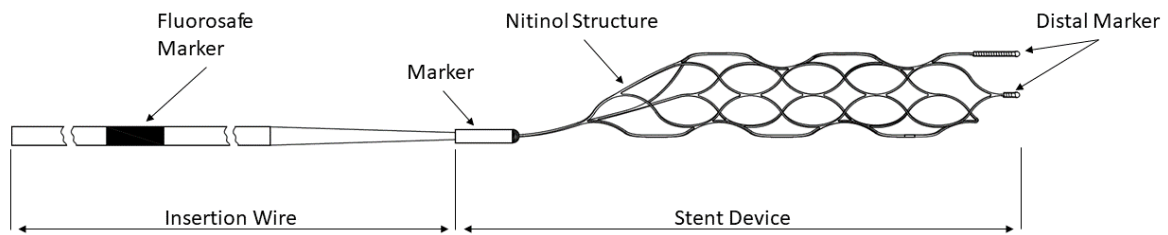


Figure 1: Schematic illustration of pRESET STANDARD in sizes 4-20 and 6-30.

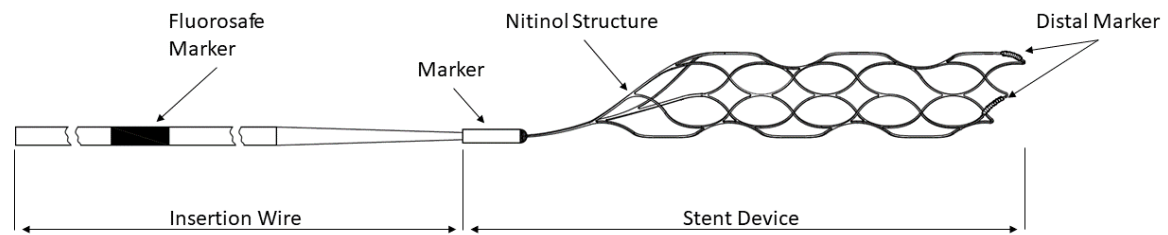


Figure 2: Schematic illustration of pRESET STANDARD D and pRESET STANDARD in sizes 5-40 and 6-50.

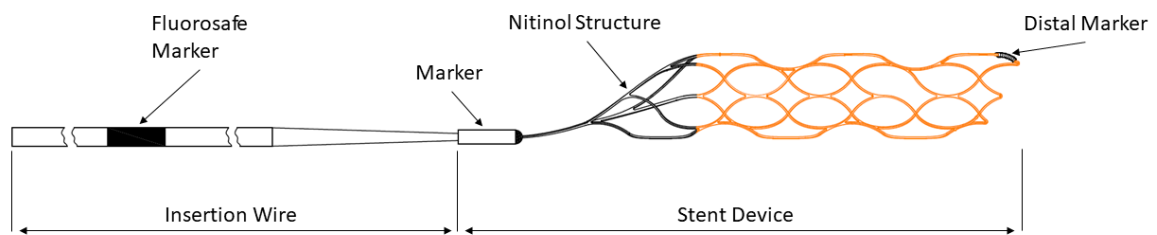


Figure 3: Schematic illustration of pRESET LUX and pRESET STANDARD LUX D.

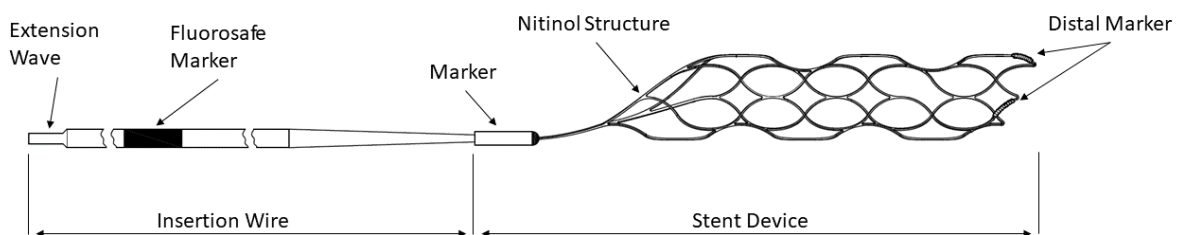


Figure 4: Schematic illustration of pRESET LITE (D).

All materials that come in contact with the patient are listed in Table 3.

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

Materials that come in contact with patient during the intervention	
Device - Short term contact	Insertion wire - short term contact
Nickel-Titanium Alloy	Nickel-Titanium Alloy (only pRESET LITE (D))
Platinum-Iridium Alloy	Cobalt-Chromium Alloy (STANDARD (D), LUX (D) and LITE D)
NAC (Noble Alloy Coating, only pRESET LUX)	Stainless Steel (only pRESET STANDARD (D) and pRESET LUX (D))
	Polytetrafluoroethylene (PTFE)

Product versions

Table 4 shows the current model sizes of the different design variants of the medical device group Thrombectomy Systems. Also, dimensions of the device when in use, can be taken from this table.

Table 4: pRESET product variants with the respective vessel diameters and effective length of the stent part

Product variant/size	Vessel diameter [mm]	Effective length [mm]	UDI
pRESET STANDARD (D)			
PRE-4-20-(D)	4	25	04260123784058
	2	27	04260123784065 (D)
PRES-5-40	5	45	04260123784089
PRE-5-40-D	2	50	04260123784096 (D)
PRE-6-30	6	37	04260123784119
	3	40	
PRE-6-30-D	6	36	04260123784126
	3	39	
PRES-6-50	6	55	04260123784140
PRE-6-50-D	3	59	04260123784157 (D)
pRESET LUX			
PRE-LUX-4-20	2	25	04260123784218
pRESET STANDARD LUX D			
PRE-LUX-4-20-D	4	25	04260123784072
	2	27	
PRE-LUX-5-40-D	5	45	04260123784102
	2	50	
PRE-LUX-6-30-D	6	36	04260123784133
	3	39	
PRE-LUX-6-50-D	6	55	04260123784164
	3	59	
pRESET LITE (D)			
PRE-LT-3-20-(D)	3	24	04260123784171 04260123784188 (D)
	2	25	
	1.5	25	
PRE-LT-4-20-(D)	4	25	04260123784195 04260123784201 (D)
	2	27	
	1.5	27	

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

There are no previous generations available.

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

N/A

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

The pRESET thrombectomy devices are used in interventional neuroradiology together with the usual equipment. This includes an angiography system, as well as sheaths, guide wires, catheters, and other products for minimally invasive use.

Microcatheter

The products of the medical device group Thrombectomy Systems are advanced to the target lesion via microcatheters. The devices are compatible with either 0.027", 0.021" or 0.017" microcatheters. An overview of the microcatheters that can be used is given in the Instructions For Use (IFU).

(Micro) Guidewire

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

Guide catheter/ Aspiration catheter

After complete deployment, the slow withdrawal of pRESET occurs under continuous aspiration via the guide catheter or aspiration catheter.

4 Risks and warnings

In addition to the contraindications described in chapter 2.3, residual risks, warnings, adverse effects as well as possible complications and the associated harm 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".
- **Residual risks** are defined as a "risk remaining after risk control measures have been taken".
- **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".

The complications and the rates (Table 5) were determined from published literature data and PMCF data on the Thrombectomy Systems (see chapter 5).

Table 5: Undesirable effects of the devices of the medical device group Thrombectomy Systems

Undesirable effects	Rate (%) for pRESET devices
Embolism	32/1,089 (2.9%)
Occlusion	0/173 (0.0%)
Thrombosis	1/25 (4.0%)
Ischemia	4/98 (4.1%)
Perforation	14/914 (1.5%)
Rupture	N/A
Dissection	11/638 (1.7%)

Undesirable effects	Rate (%) for pRESET devices
Arterial Lesions	N/A
Vasospasm	59/646 (9.1%)
Pseudoaneurysm	8/271 (3.0%)
Intracranial Haemorrhage	382/1,208 (31.6%)
Allergic Reaction	N/A
Infection	N/A
Infarction	2/173 (1.2%)
Neurological Deficit	10/152 (6.6%)
Persistent Vegetative State	N/A
Death	See Mortality (Day 90)
Other:	
Access Site Complication	13/444 (2.9%)
Altered Consciousness	N/A
Cardiac Complication	N/A
Cerebral Oedema	N/A
Extravasation	3/176 (1.7%)
Haematoma	N/A
Brain Herniation	N/A
Mass Effect or Intracranial Tumour	1/173 (0.6%)
Necrosis	N/A
Organ Failure	N/A
Pain	N/A
Puncture	1/271 (0.4%)
Renal Complications	N/A
Respiratory Complications/Pneumonia	N/A
Systemic Bleeding	N/A
Vascular Deformity	N/A
Worsening of Pre-Existing Condition	N/A

4.2 Warnings and precautions

Warnings

If excessive resistance is encountered during the delivery of the pRESET Thrombectomy Device, discontinue the delivery and identify the cause of the resistance. Advancement of the pRESET Thrombectomy Device against resistance may result in device damage and/or patient injury. In case of major resistance during insertion of the pRESET thrombectomy device, remove the device and eventually the microcatheter and catheterize again.

Only introduce the device in sufficiently large target vessels to avoid device damage and/or patient injury.

Never push the pRESET beyond the distal tip of the microcatheter. To do so may result in dissection or perforation of the concerning artery.

- Some resistance may be observed at this point; the more distal the device has been introduced, the more resistance that may be encountered. Always pull gently, never abruptly or in steps!

- In case of excessive retraction resistance, the reintroduction of the microcatheter for splinting the pRESET insertion wire is recommended. If the microcatheter cannot be pushed completely over the device, remove both the device and microcatheter as a unit.

Do not use pRESET thrombectomy device more than three (3) times in the same patient during the course of one intervention for vessel and device safety.

The device is for single use only. Do not reuse in another patient. Do not reprocess or re-sterilize. Reprocessing and re-sterilization increase the risks of patient infection and/or death as well as compromised device performance.

Do not use the pRESET thrombectomy device in microcatheters with IDs larger than recommended. Microcatheters or other catheters with larger inner diameters may lead to a stressful passage for the pRESET thrombectomy device causing a disconnection of the device or damage to parts of it.

Apply the device only under continuous fluoroscopic monitoring.

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.

The pRESET thrombectomy device is delicate and requires careful handling. Never push the microcatheter onto the device against resistance. Never twist/torque/kink/bend the insertion wire. If necessary, remove pRESET thrombectomy device via microcatheter.

Forceful pulling or pushing or twisting on the insertion wire could lead to separation of the device from said insertion wire. It is recommended that the separated parts be retrieved using a snare device.

The deployed pRESET thrombectomy device must not be retracted through implanted vascular implants (e.g., stents or flow diverters)

Persons with 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 pRESET thrombectomy device.

Visually inspect all sterile barrier systems, that are labeled as sterile, immediately prior to use. Do not use the device if breaches in sterile barrier system integrity are evident.

Any damaged or unintentionally opened product must be exchanged and replaced with an undamaged and 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 -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.

The device with the insertion wire and, where necessary, packaging components or other components used during the intervention must be disposed of appropriately in marked containers. Failure to dispose of the product correctly can lead to an increased risk of infection for the physician or patient.

Use is only permissible prior to the expiration date, as sterility is not guaranteed otherwise.

The device contains cobalt, which is a CMR-classified substance.

Precautions

- Do not use the pRESET device other than defined in the indications or intended use.
- The product must be checked for damage before use. Do not use deformed or damaged products, as function cannot be assumed otherwise.
- Use the product only in microcatheters listed in the compatibility table.
- For flushing, place the introducer sheath of the product 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.
- Pay attention during device passage from introducer sheath into microcatheter that the introducer sheath does not move back proximally. If this happens the instrument and/or the insertion wire may be kinked, bend and/or weakened and therefore might become damaged.
- In case of excessive retraction resistance the reintroduction of the microcatheter for splinting of the pRESET thrombectomy device insertion wire or removal of the product is recommended. If the microcatheter cannot be pushed completely over the device remove both, device and microcatheter as a unit.
- If vasospasm is suspected in the affected vessel region, all necessary measures, e.g., medication, should be taken before pRESET thrombectomy device treatment.
- Between the applications the device must be cleansed of blood and thrombus and inspected for damages.
- For the use of the pRESET in the posterior circulation, the condition of the vertebral artery contralateral to the vessel catheterized with the guiding catheter is important:
 - o If this artery is not supplying the basilar artery, no further action is required.
 - o If this artery is fully patent, aspiration on the guiding catheter will only affect the basilar artery when the contralateral vertebral artery is temporarily blocked. This may be achieved preferably with a shape adaptive balloon catheter or by probing the vertebral artery with a diagnostic catheter having an occluding effect.

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) were initiated.

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

The following summarizes the clinical evaluation results and results of the post-market clinical follow-up (PMCF). Both favorable and unfavorable data regarding conformity with the general safety and performance requirements (GSPRs) of all devices of the medical device group Thrombectomy Systems are objectively considered.

Performance and Safety data are shown in Table 6 and Table 7.

Clinical investigations:

- The national single-arm prospective Post-Market Clinical Follow-Up study ARTESp (NCT02437409) [1], aimed to assess the efficacy and safety of the pRESET stent retriever (pRESET STANDARD 4-20 and pRESET STANDARD 6-30) for the treatment of intracranial vessel occlusion. pRESET proved to be safe and effective for the treatment of acute intracranial vessel occlusion.
- The PROST trial (ClinicalTrials.gov identifier: NCT03994822) [2] aimed to evaluate the safety and effectiveness of pRESET for the treatment of acute ischemic stroke within 8h of symptom onset due to large vessel occlusion and to compare safety and effectiveness of the predicate device, Solitaire Revascularization Device (Medtronic). Among patients with acute ischemic stroke due to large vessel occlusion, thrombectomy with the pRESET stent retriever was noninferior to thrombectomy with the Solitaire stent retriever, with respect to all prespecified primary and secondary safety and efficacy end points. pRESET offers a safe and effective option for flow restoration and disability reduction in patients with LVO stroke.

Internal PMCF data:

During the DISTAL trial, 25 patients were treated with a pRESET Thrombectomy device. Successful recanalization (mTICI $\geq$ 2b) was achieved in 21/25 patients (84%). In total, 9 adverse events occurred.

Survey data:

- In total, 56 cases were performed during Limited Market Release (LMR) for pRESET STANDARD 4-20 and 6-30 (20.8.2022 and 01.06.2012). It was shown that the devices are safe and effective (oTICI $\geq$ 2b: 87.5%) for the acute treatment of ischemic stroke with low complication rates.
- First clinical experiences in 20 patients after CE-certification (05.09.2019) show that pRESET STANDARD 5-40 is safe and effective for the treatment of acute stroke (oTICI $\geq$ 2b: 100%).
- The first experiences with pRESET STANDARD 6-50 showed successful reperfusion (oTICI $\geq$ 2b: 96.2%) with low complication rates. Only one pass was needed to achieve oTICI $\geq$ 2b with pRESET STANDARD 6-50 in 60.9%.
- With pRESET LUX 4-20, 38 cases were documented. In 31 cases a single pRESET LUX 4-20 was used to treat the ischemic stroke. The sufficient recanalization rate (o-TICI $\geq$ 2b) after the usage of pRESET was 91.66%.
- Further experience (n=87) with the devices of the medical device group “Thrombectomy Systems” showed a successful reperfusion (o-TICI $\geq$ 2b) in 88.2% with low complication rates.
- Data (indirect evidence) from two surveys primarily conducted for a microcatheter and an aspiration catheter showed TICI $\geq$ 2b was achieved in 10/12 patients (83.3%) and showed a successful reperfusion (eTICI $\geq$ 2b) 90.1% for cases conducted with a pRESET Thrombectomy device. Complications regarding pRESET were not reported.

Undesirable effects (Table 5), performance (Table 6) and safety data (Table 7) are presented within this SSCP.

5.1 Summary of clinical data related to equivalent device

pRESET device variants are considered to be equivalent to each other. Data applicable for all device variants are shown in chapter 5.

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

Within the scope of the respective first MDD conformity assessment, clinical data were collected and verified by the notified body, so that the MDD-CE certification was granted for each of the device variants.

The clinical data prior to MDD-CE-certification demonstrate that all pRESET variants are effective and safe and suitable for the intended purpose as described in the Instruction For Use (IFU).

5.3 Summary of clinical data from other sources

In addition to the clinical investigations [1, 2] summarized in chapter 5, different articles about pRESET thrombectomy devices have been published [3-9] and data have been evaluated in meta-analyses [10, 11].

- Serna Candel et al., 2021 [7] reported the results of aspiration-assisted mechanical thrombectomy of acute isolated occlusion of the middle cerebral artery in the M1 segment with pRESET 5-40 in comparison to pRESET 4-20 in 170 patients.
- Further experiences with the pRESET STANDARD and pRESET LITE were published by e.g., Schwaiger et al., 2016 [6], Kraehling et al., 2023 [3], Wang et al., 2024 [9] and Sporns et al. 2024 [8]. Kurre et al. reported about the treatment with pRESET [5] and pRESET LITE [4].

Performance and safety data and clinical complications are shown in Table 5, Table 6 and Table 7.

5.4 An overall summary of the clinical performance and safety

Performance and safety data obtained from PMCF clinical data collection and literature data are shown in Table 6 and Table 7.

The performance and safety of pRESET Thrombectomy devices is comparable to similar devices.

Table 6: Performance data of pRESET devices (Literature and PMCF data)

Clinical Outcome Parameter	Author and Ref	Model & Variant	Rate	Calculated Rate
TICI Scale Score	Kraehling <i>et al.</i> (2023)	PRE-6-50	mTICI $\geq$ 2c: 82/98 (83%) mTICI $\geq$ 2b: 95/98 (97%) [$\leq$ 3 Passes]	STANDARD TICI 3: 183/271 (67.5%) TICI $\geq$ 2c: 293/441 (66.4%) TICI $\geq$ 2b67: 92/109 (84.4%) TICI $\geq$ 2b50: 654/760 (86.1%) LITE TICI 3: 58/114 (50.9%) TICI $\geq$ 2c: 165/251 (65.7%) TICI $\geq$ 2b50: 258/317 (81.4%) LUX N/A PRODUCT FAMILY TICI 3: 241/385 (62.6%) TICI $\geq$ 2c: 458/692 (65.3%) TICI $\geq$ 2b67: 92/109 (84.4%) TICI $\geq$ 2b50: 912/1077 (84.7%)
	Kurre <i>et al.</i> (2017)	PRE-LT	mTICI 3: 44/90 (48.9%) mTICI $\geq$ 2b: 63/90 (70.0%)	
	Kurre <i>et al.</i> (2014)	PRE-6-30 PRE-4-20	mTICI 3: 183/271 (67.5%) [$\leq$ 3 Passes] mTICI $\geq$ 2b: 207/271 (76.4%) [$\leq$ 3 Passes] mTICI 3: 216/271 (79.7%) mTICI $\geq$ 2b: 257/271 (94.8%)	
	Nogueira <i>et al.</i> (2024)	PRE-6-30 PRE-5-40 PRE-4-20	eTICI $\geq$ 2c: 94/173 (54.60%) [$\leq$ 3 Passes] eTICI $\geq$ 2b50: 146/173 (84.39%) [$\leq$ 3 Passes]	
	Prothmann <i>et al.</i> (2017)	PRE-6-30 PRE-4-20	oTICI $\geq$ 2b: 92/109 (84.4%) [$\leq$ 5 Passes]	
	Schwaiger <i>et al.</i> (2016)	PRE-4-20	mTICI $\geq$ 2b: 39/48 (81.3%)	
	Serna Candel <i>et al.</i> (2021)	PRE-5-40 PRE-4-20	mTICI $\geq$ 2c: 117/170 (68.8%) mTICI $\geq$ 2b: 167/170 (98.2%)	
	Sporns <i>et al.</i> (2024) [8]	PRE-LT-3-20	mTICI3: 14/24 (58.3%) mTICI $\geq$ 2c: 22/24 (92%)	
	Wang <i>et al.</i> (2024)	PRE-LT	eTICI $\geq$ 2c: 143/227 (65%) eTICI $\geq$ 2b: 195/227 (89%)	
	Internal PMCF Data	PRE-6-50 PRE-6-30 PRE-5-40 PRE-4-20 PRE-LT-4-20 PRE-LT-3-20 PRE-LUX-4-20	N/A	PRODUCT FAMILY TICI $\geq$ 2b: 243/271 (89.7%)
First Pass Effect	Kraehling <i>et al.</i> (2023)	PRE-6-50	mTICI $\geq$ 2b: 61/98 (62%)	STANDARD TICI 3: 37/166 (22.3%) TICI $\geq$ 2c: 157/343 (45.8%)

Clinical Outcome Parameter	Author and Ref	Model & Variant	Rate	Calculated Rate
	Nogueira <i>et al.</i> (2024)	PRE-6-30 PRE-5-40 PRE-4-20	eTICI3: 37/166 (22.29%) eTICI≥2c: 76/173 (43.68%) eTICI≥2b67: 90/166 (54.22%) eTICI≥2b50: 102/166 (61.45%)	TICI≥2b67: 90/166 (54.2%) TICI≥2b50: 257/434 (59.2%) <u>LITE</u> TICI≥2c: 68/227 (31%)
	Serna Candell <i>et al.</i> (2021)	PRE-5-40 PRE-4-20	mTICI≥2c: 81/170 (47.6%) mTICI≥2b: 94/170 (55.3%)	<u>LUX</u> N/A
	Wang <i>et al.</i> (2024)	PRE-LT	mTICI≥2c: 68/227 (31%)	<u>PRODUCT FAMILY</u> TICI 3: 37/166 (22.3%) TICI≥2c: 225/570 (39.5%) TICI≥2b67: 90/166 (54.2%) TICI≥2b50: 257/434 (59.2%)
	Internal PMCF data (survey data)	PRE-6-30 PRE-5-40 PRE-4-20 PRE-6-50 PRE-LT-4-20 PRE-LUX-4-20	N/A	<u>PRODUCT FAMILY</u> TICI≥2b67: 45/69 (65.2%)
mRS Score	Nogueira <i>et al.</i> (2024)	PRE-6-30 PRE-5-40 PRE-4-20	Day 90 (mRS≤2): 95/173 (54.91%) Day 90 (mRS≤1): 70/173 (40.46%)	<u>STANDARD</u> Day 90 (mRS≤2): 323/710 (45.5%) Day 90 (mRS≤1): 122/269 (45.4%) Day 90 (mRS 0): 23/96 (24.0%)
	Kurre <i>et al.</i> (2017)	PRE-LT	Day 90 (mRS≤2): ~34.0% Day 90 (mRS≤1): ~26.0% Day 90 (mRS 0): ~17.0%	
	Kurre <i>et al.</i> (2014)	PRE-6-30 PRE-4-20	Day 90 (mRS≤2): 107/271 (39.5%)	<u>LITE</u> Day 90 (mRS≤2): 87/143 (60.8%) Day 90 (mRS≤1): 46/143 (32.3%) Day 90 (mRS 0): 6/24 (25.0%)
	Prothmann <i>et al.</i> (2017)	PRE-6-30 PRE-4-20	Day 90 (mRS≤2): 60/96 (62.5%) Day 90 (mRS≤1): 52/96 (54.2%) Day 90 (mRS 0): 23/96 (24.0%)	
	Schwaiger <i>et al.</i> (2016)	PRE-4-20	Discharge (mRS≤2): 17/46 (37.0 %) ^d Follow-Up (mRS≤2): 18/43 (41.9%) ^d	<u>LUX</u> N/A

Clinical Outcome Parameter	Author and Ref	Model & Variant	Rate	Calculated Rate
	Serna Candell <i>et al.</i> (2021)	PRE-5-40 PRE-4-20	Day 90 (mRS≤2): 61/170 (35.9%)	PRODUCT FAMILY Day 90 (mRS≤2): 444/921 (48.2%) Day 90 (mRS≤1): 178/437 (40.7%) Day 90 (mRS 0): 33/145 (22.8%)
	Sporns <i>et al.</i> (2024)	PRE-LT-3-20	Day 90 (mRS≤2): 18/24 (75.0%) Day 90 (mRS≤1): 13/24 (54.2%) Day 90 (mRS 0): 6/24 (25.0%)	
	Wang <i>et al.</i> (2024)	PRE-LT	Day 90 (mRS≤2): 69/119 (58%) Day 90 (mRS≤1): 33/119 (28%)	
	Internal PMCF data (DISTAL)	PRE-6-50 PRE-4-20 PRE-LT-4-20 PRE-LT-3-20	Day 90 (mRS≤2): 16/25 (64.0%) Day 90 (mRS≤1): 10/25 (40.0%) Day 90 (mRS 0): 4/25 (16.0%)	

^a The rates are manually calculated based on the total number of patients/vessels achieving the outcome by the total number of patients/vessels from the included data. The pRESET Thrombectomy Device may have been used alone or in combination with other endovascular therapy, including aspiration catheters, to achieve the clinical outcome. The pRESET Thrombectomy Device may have been used for more than 3 passes to achieve the clinical outcome, or the clinical outcome may have been achieved following rescue with other devices. Data where the pRESET Thrombectomy Device was used as rescue therapy, i.e. not the first-choice treatment, are excluded.

Table 7: pRESET Thrombectomy Device Safety (Literature and PMCF data)

Clinical Outcome Parameter	Ref	Model & Variant	Rate	Calculated Rate ^a
Mortality	Kurre <i>et al.</i> (2017)	PRE-LT	Day 90 (all-cause): ~26% ^b	STANDARD Day 90 (all-cause): 88/482 (18.3%) LITE Day 90 (all-cause): 15/143 (10.5%) LUX N/A PRODUCT FAMILY Day 90 (all-cause): 102/601 (17.0%)
	Kurre <i>et al.</i> (2014)	PRE-6-30 PRE-4-20	Day 90 (all-cause): ~24% ^c	
	Nogueira <i>et al.</i> (2024)	PRE-6-30 PRE-5-40 PRE-4-20	24 h (SADE): 0/173 (0.0%) Day 90 (all-cause): 25/173 (14.5%) Day 90 (stroke-related): 7/173 (4.1%)	
	Prothmann <i>et al.</i> (2017)	PRE-6-30 PRE-4-20	Day 90 (all-cause): 7/96 (7.3%)	
	Schwaiger <i>et al.</i> (2016)	PRE-4-20	Day 90 (all-cause): 8/43 (18.6%)	
	Serna Candell <i>et al.</i> (2021)	PRE-5-40 PRE-4-20	Day 90 (all-cause): 48/170 (28.2%)	

Clinical Outcome Parameter	Ref	Model & Variant	Rate	Calculated Rate ^a
	Sporns et al. (2024)	PRE-LT-3-20	Day 90: 1/24 (4.0%)	PRODUCT FAMILY 90 Day: 3/25 (12.0%)
	Wang et al. (2024)	PRE-LT	Day 90 (all-cause): 14/119 (12%)	
	Internal PMCF data (DISTAL)	PRE-6-50 PRE-4-20 PRE-LT-4-20 • PRE-LT-3-20	90 Day: 3/25 (12.0%)	
sICH	Kraehling et al. (2023)	PRE-6-50	Post-treatment (ECASS III): 5/98 (5%)	STANDARD 7/589 (1.2%) LITE 2/98 (2.0%) LUX N/A PRODUCT FAMILY 9/687 (1.3%)
	Kurre et al. (2017)	PRE-LT	48 h (ECASS): 0/74 (0%)	
	Nogueira et al. (2024)	PRE-6-30 PRE-5-40 PRE-4-20	36 h (SITS-MOST): 0/173 (0.0%)	
	Prothmann et al. (2017)	PRE-6-30 PRE-4-20	24 h (ECASS: ↑NIHSS≥3 points): 2/100 (2%)	
	Schwaiger et al. (2016)	PRE-4-20	24 h (ECASS): 0/48 (0%)	
	Serna Candel et al. (2021)	PRE-5-40 PRE-4-20	36 h (ECASS II): 0/168 (0%)	
	Sporns et al. (2024)	PRE-LT-3-20	2/24 (8.0%)	

^a The rates are manually calculated based on the total number of patients/vessels achieving the outcome by the total number of patients/vessels. The pRESET Thrombectomy Device may have been used alone or in combination with other endovascular therapy, including aspiration catheters, to achieve the clinical outcome. The pRESET Thrombectomy Device may have been used for more than 3 passes to achieve the clinical outcome, or the clinical outcome may have been achieved following rescue with other devices. Publications where the pRESET Thrombectomy Device was used as rescue therapy, i.e. not the first-choice treatment, are excluded. Case Reports are excluded. Publications with data not presented in a n/N format are excluded.

^b Extrapolated from publication Figure 1

^c Extrapolated from publication Figure 2

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 Thrombectomy Systems. This includes e.g., market feedback (e.g., customer claims), literature analysis of phenox's own products as well as literature and clinical data analysis regarding equivalent or similar devices and analysis of safety databases (e.g., BfArM, FDA-MAUDE). Moreover, survey data will be collected.

The ETIS registry (ClinicalTrials.gov identifier: NCT03776877), DISCOUNT trial (ClinicalTrials.gov identifier: NCT05030142) include the investigation of pRESET Thrombectomy devices. The aim of the ETIS registry is to determine the non-inferiority of pRESET first-line thrombectomy compared with standard first line thrombectomy (with approved devices) to achieve successful reperfusion. The DISCOUNT trial evaluates the efficacy in terms of good clinical outcome at 3 months of MT associated with the BMT over the BMT alone in distal occlusion.

6 Possible diagnostic or therapeutic alternatives

In addition to mechanical thrombectomy with stent retrievers, such as pRESET, the following alternative treatments are available for the treatment of acute ischemic stroke:

- **Thrombolysis (IV & IA)**

Due to specific inclusion and exclusion criteria, intravenous or intra-arterial lysis therapy with r-tPA has limited use in a large number of patients. Another limitation for this treatment is the time window of 4.5 hours after stroke onset .

- **Aspiration thrombectomy**

Aspiration thrombectomy consists of navigating a large-bore catheter up to the proximal end of the thrombus. Once in place, the aspiration catheter is then connected to an aspiration system such as a pump or a negative-pressure syringe. After waiting for a few minutes, the aspiration catheter is then slowly withdrawn.

7 Suggested profile and training for users

The products of the medical device group Thrombectomy Systems may only be used in a (neuro-) radiological clinic by specialized, appropriately trained physicians who are experienced in the use of thrombectomy devices. 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: 2009/2012)
- EN ISO 25539-2 Cardiovascular implants (Status: 2020)

- ISO 17327-1 Non-active surgical implants - Implant coating - Part 1: General requirements (Status: 2018)

9 Revision history

Table 8: 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
Rev. B	17.03.2024	Formal adaptation of the REF and e-mailaddress	☒ Yes Language of validation: English ☐ No
Rev. C	n/a	Update of the SSCP to align with the updated Clinical Evaluation	☐ Yes Language of validation: English ☒ No
Rev. D	07.08.2026	Update of the SSCP to align with the updated Clinical Evaluation	☒ Yes Language of validation: English ☐ No

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