Summary of Safety and Clinical Performance

Neuro-Patch®

SSCP identifier:	BDoCS-AIM-029639
Manufacturer contact details	
Legal manufacturer name:	Aesculap AG
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Part 1: Intended for healthcare professionals

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.
The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.
The following information is intended for users/healthcare professionals.

List of abbreviation / glossary

AE	Adverse event
Basic UDI-DI	Basic Unique device identification device identifier
CAPA	Corrective and preventive action
CER	Clinical evaluation report
CSF	Cerebrospinal fluid
EO	Ethylene oxide
FSCA	Field safety corrective action
FSN	Field safety notice
MRI	Magnetic Resonance Imaging
PSMC	Pseudomeningocele
PUR947	Polyester urethane
SAE	Serious adverse event
SOTA	State-of-the-art
SSCP	Summary of Safety and Clinical Performance
SSI	Surgical Site Infection

1 Device identification and general information

1.1 Device trade name

Neuro-Patch®

Table 1. Neuro-Patch – Article list

Reference Number	Description	Content
1064002	Neuro-Patch® 12 cm x 14 cm	1 piece
1064010	Neuro-Patch® 6 cm x 14 cm	1 piece
1064020	Neuro-Patch® 8 cm x 9 cm	1 piece
1064029	Neuro-Patch® 6 cm x 8 cm	1 piece
1064037	Neuro-Patch® 4 cm x 10 cm	1 piece
1064040	Neuro-Patch® 5 cm x 6 cm	1 piece
1064110	Neuro-Patch® 4 cm x 5 cm	1 piece
1064122	Neuro-Patch® 2 cm x 10 cm	1 piece
1064123	Neuro-Patch® 1.5 cm x 3 cm	1 piece
1064045	Neuro-Patch® 4 cm x 5 cm	2 pieces
1064053	Neuro-Patch® 2 cm x 10 cm	2 pieces
1064061	Neuro-Patch® 1.5 cm x 3 cm	2 pieces

1.2 Manufacturer's name and address

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen/Germany

1.3 Manufacturer's single registration number (SRN)

Manufacturer's single registration number: DE-MF-000005504

1.4 Basic UDI-DI

Basic UDI-DI for Neuro-Patch®: 4039239000001401ZR

1.5 Medical device nomenclature description

P900403 „NON-BIODEGRADABLE DEVICES, FILLER AND RECONSTRUCTIVE"

1.6 Class of device

According to the MDR 2017/745 Annex VIII, rule 8.2 Neuro-Patch® can be assigned as a class III medical device.

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

Neuro-Patch® is CE-certified since 1996.

1.8 Authorized representative if applicable; name and the SRN

Not applicable.

1.9 NB's name (the NB that will validate the SSCP) and the NB's single identification number

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München

Single identification number: 0123

2 The intended purpose of the device, indications, contraindications and target populations

According to the instructions for use, IFU (12157732), the following information is provided to the user.

2.1 Intended purpose

Neuro-Patch® is used in neurosurgery as dura mater replacement.

2.2 Indication(s) and target population(s)

Indications

- For covering cerebral and cerebellar dural defects
- For cerebral decompression surgery
- For covering spinal dural defects
- For spinal decompression surgery

Intended patient population

Regarding the intended target population, restrictions are defined by the contraindications.

2.3 Contraindications and/or limitations

Neuro-Patch should not be applied:

- In infected areas
- In open cerebrocranial traumata
- In open spina bifida
- In case of known hypersensitivity against implant materials; for fixation materials please note the corresponding instructions for use
- In any application area that is not mentioned in "Indications"

3 Device description

3.1 Description of the device

Neuro-Patch® is a non-absorbable, fine fibrillar microporous membrane (Figure 1) made from high-purity, aliphatic polyester urethane. The structure of Neuro-Patch® is characterized by open micropores which are aimed at facilitating the infiltration of fibroblasts.

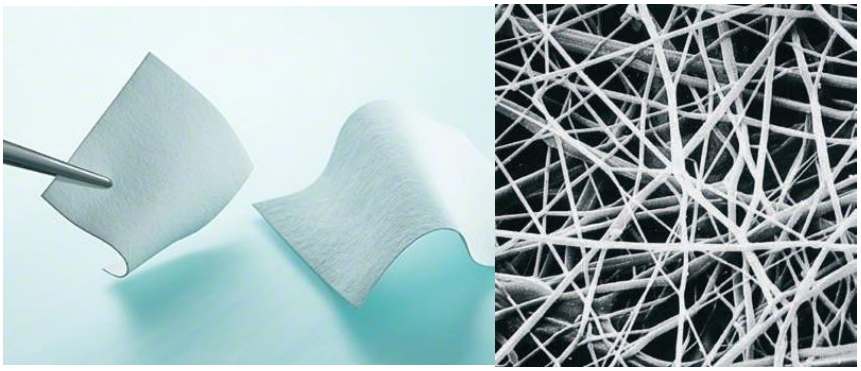

Figure 1. Product image (left) and microporous structure (right) of Neuro-Patch®.

The product belongs to the group of neurosurgical implants.

- During the intended use, the following organs/tissue/body fluids come in contact with the device: brain, spinal cord, bone, dura mater, cerebrospinal fluid as well as blood.
- The application of the device is invasive.
- The application period of the device is long-term.
- The device is intended for clinical users: Surgeon with required knowledge about the surgical technique and surgical training who is aware of the in vivo characteristics of the product, operating room personnel (set-up, handling, and functional check).
- Neuro-Patch® is a single use device and will be delivered sterile (sterilization method: ethylene oxide).
- There are no restrictions regarding the intended patient population additional to the indications/contraindications.
- The device does not contain pharmaceutical components, animal or human tissue; is neither derived from blood products nor blood products themselves.
- The device is not radioactive.
- No changes have been made to the product since the market launch of Neuro-Patch®.

Operating principles and mode of action

Neuro-Patch® is used to restore a liquid-tight dural closure. Before implantation, Neuro-Patch® needs to be cut into the required shape based on the dural defect size. The implant must be sutured using non-degradable sutures. It is recommended to achieve tension-free embedding of the implant.

Following implantation, the microporous structure of Neuro-Patch® (Figure 1) facilitates the infiltration of fibroblasts. These cells secrete collagen, contributing to the development of a thin neodural membrane facilitating the integration of the implanted Neuro-Patch® with the surrounding native dura mater over time.

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

Since the market launch of Neuro-Patch® in 1996, no changes to the product has been made. No variants of Neuro-Patch®, other than the different product and packaging sizes, are available.

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

Neuro-Patch® must be sutured with nonabsorbable suture material (polyester, polypropylene) and can be additionally fixed with fibrin sealant.

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

There are no other devices nor products which are intended to be used in combination with the device.

4 Risks and warnings

4.1 Residual risks and undesirable effects

Potential complications that the manufacturer is currently aware of:

- Cerebrospinal fluid leakage (CSF)
- Surgical site infection (SSI)
- Adhesion
- Foreign body reaction (inflammation, granuloma, allergic reaction)

Table 2. Quantitative data on side effects.

Side effect	**Complaints data** (complaints/units sold over past 5 years)	**Clinical data – PMCF MiDura-Study** (294 patients)	Probability of occurrence*
CSF leak	0.004%	2.72%	Improbable** < 0.05%
SSI	0.002%	2.04%	Improbable < 0.05%
Adhesion	0.00%	0.00%	Improbable < 0.05%
Foreign body reaction	0.00%	0.00%	Improbable < 0.05%

* Considers weighted average of reported side effect derived from both Complaints data and Clinical data from the MiDura Study.
** The lowest medical occurrence according to the product risk analysis

4.2 Warnings and precautions

As per Instruction for Use

General safety information

To prevent damage caused by improper setup or operation, and to avoid compromising manufacturer warranty and liability:

- Use the product only according to this document.
- Follow the safety information in this document.
- Ensure that the product and its accessories are only operated and used by qualified personnel.
- Store any new or unused products in a dry, clean, and safe place.
- Keep this document accessible to the user.

Note

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

Notes on surgical procedures

It is the user's responsibility to ensure that the surgical procedure is performed correctly. Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product.
Aesculap AG is not responsible for complications caused by:

- incorrect indication or implant selection
- incorrect surgical technique
- incorrect combination of implant components
- combination with components from other manufacturers not approved by Aesculap AG
- exceeding the limitations of the treatment method or non-observance of essential medical precautions

The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

MRI safety information

MRI examinations using magnetic fields of 1.5 or 3.0 tesla do not present an additional risk to implant bearers as the product is made of non-metallic material.

Sterility and storage

The product has been EO-sterilized (ethylene oxide) and is supplied in sterile packaging. The safe sterile provision of the product is only guaranteed if the sterile packaging is undamaged and unopened and the use-by date has not passed.

- Remove products from their original protective packaging only just prior to application
- Visually inspect the product packaging to ensure that the sterile barrier system is intact.
- Do not use products from open or damaged sterile packaging.
- Do not use the product after its use-by date.
- Do not reuse the product.
  The processing of the product affects its functionality. Risk of injury, illness or death due to soiling and/or impaired functionality of the product
- Do not reprocess the product.
- Store the product at 20 - 30°C.
- Store sterile packaged products in a dry, dark and temperature-controlled room that is protected against dust and do not expose them to extreme temperatures or ionizing radiation.
- Transport and handle products with care to prevent damage to the packaging and products.

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

No Field Safety Notices (FSN) nor Field Safety Corrective Actions (FSCA) were necessary for the products in the last five years.

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

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

Not applicable.

Effective

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

Clinical study by Laun and Grundmann

The aim of the prospective, multi-center study initiated in 1992 and led by Laun and Grundmann, was to evaluate the safety and performance of Neuro-Patch® in neurosurgical head surgery in terms of intraoperative handling, immediate postoperative complications and long-term compatibility of the product.

In total, 317 patients (160 female, 157 male) were enrolled in the study (5 clinics) and followed up for up to one year postoperatively. The average age of the subjects was 50 years (range 1-86 years). Neuro-Patch® was mainly used in the treatment of tumor diseases (n=271).

With regard to the intraoperative performance and handling properties of the Neuro-Patch®, CSF tightness and seam tearing, as well as suturing, cutting and modelling were assessed, respectively. The ability of Neuro-Patch® to provide an immediate impermeable barrier to CSF was successful in 98%. The handling properties were in majority judged by the surgeons as good.
Intraoperative complications were observed in 32 cases (10.1%). The most common were brain swelling and bleeding. A causal relationship with the application of Neuro-Patch® was not evident in any case.

The investigators conclude that Neuro-Patch® is suitable for the use as a dura substitute due to its low complication rate and good handling characteristics.

5.3 Summary of clinical data from other sources, if applicable

PMCF MiDura-Study

"Multicentric, international, prospective, observational, study using Neuro-Patch® in duraplasty in neurosurgery" (MiDura-Study) has been initiated in 2019 as a proactive post-market clinical follow-up (PMCF) measure to collect systematically and proactively data regarding the performance of Neuro-Patch® under daily clinical practice when used as intended by the manufacturer.

In total, 328 patients have been recruited across four study sites. Recruitment has been completed. Data from 294 patients has been analyzed.

In total 50 adverse events (AEs) occurred (in 42 patients), out of which 48 were classified as severe adverse event (SAE). Out of these, only seven SAEs had a (possible) causal relationship to Neuro-Patch®. Four of them were CSF leaks (1.42%) and three SSI (1.06%). The therapeutic measures performed due to these SAEs were in all cases operative. Neuro-Patch® was removed in six cases.

There were also three SSI and six additional CSF-related complications that had no (possible) causal relationship to Neuro-Patch®. Considering the total number of patients (n=294), the overall incidence rate of CSF leak and SSI was 2.72% (8 patients) and 2.04% (6 patients), respectively.
All CSF leaks that occurred were in the posterior fossa region. This area is more prone to CSF leaks because of higher hydrostatic pressure. Posterior fossa surgery has long been known to be associated with increased hydrodynamic complication rates.

The intraoperative handling characteristics of Neuro-Patch® were evaluated by surgeons on a five-point Likert Scale from excellent to poor. The surgeon´s overall satisfaction with the implant was reported in 14% as excellent, in 53% as very good and in 16% as good.

IMS Form | Aesculap AG | Author: Dr. S. Maenz | Document Number: SA-DE13-M-4-1-11-512-1-C-EN | Version: 3.0 | 2022-05-13

In summary, the observed CSF leak rate of 2.72% is very low and falls within the normal range of expected CSF leaks when compared to the literature (see Table 3). The current clinical results of MiDura-Study allow to conclude that Neuro-Patch® is a safe and effective dura substitute with very good handling properties.

Expert Reports

Clinical experience with Neuro-Patch® has been documented across several neurosurgical departments between 2006 and 2020, covering more than 3900 surgical procedures. The product has been applied in a broad range of indications, including cranial and spinal dural repairs, trauma-related defects, surgeries involving elevated intracranial pressure, and operations associated with a high risk of infection, such as those involving the frontal sinus.

In all reported cases, Neuro-Patch® demonstrated a high level of safety. No postoperative infections or inflammatory responses attributable to the product were observed. There were no reports of CSF leak or adhesion of the implant to brain tissue. The material was also successfully used in pediatric patients, indicating no restrictions related to patient age.

Clinicians highlighted several key performance benefits. Neuro-Patch® was noted for its immediate availability and ease of handling during surgery. Its mechanical properties offered a favorable balance between elasticity and strength, facilitating secure suturing and effective adaptation to dural defects. The product consistently enabled watertight dural closure and, in cases requiring re-operation, reduced the extent of scar tissue formation on the cerebral cortex, thereby simplifying and improving surgical outcomes in follow-up procedures.

Some limitations were also identified. The stiffness of the material may, in certain cranial procedures, encourage the formation of CSF pockets (liquor cushions). Additionally, clinicians recommended the availability of smaller patch sizes (1–2 cm^2) and narrower strip formats (e.g., 1 cm × 5 cm) to better accommodate minimally invasive and spinal applications.

Overall, the clinical use of Neuro-Patch® confirms its safety and effectiveness for neurosurgical dural repair, with areas for potential improvement primarily related to product sizing.

Customer survey

Between October 2019 and June 2020, 47 customers of Neuro-Patch® have been asked to fill a questionnaire on their use of Neuro-Patch® in clinical routine.

The results of the questionnaire show that the majority of users rate the handling and performance parameters as excellent or very good in all fields (ability to cut, adaption to anatomical structures, liquid tightness, tensile strength and suture retention strength). In total, more than 90% of the users were satisfied with the performance of the Neuro-Patch®. No one rated the performance as poor and only a minority rated any of the parameters as "fair".

Literature on the product

In total, 23 publications have been identified for Neuro-Patch® used in various indications. (1–23) The most common complications reported were CSF leak and SSI. The overall occurrence rates, however, lie in the acceptance criteria established in the framework of the state-of-the-art (SOTA) literature review, and are considered acceptable. The identified clinical data from the literature on Neuro-Patch® indicates a safe and clinically effective performance within the intended purpose.

Only one publication with unfavorable findings were identified, i.e., Malliti et al., conclude that the use of Neuro-Patch® increases the risk of wound infection. (21) These findings, however, are contradictory to outcomes from study by Li et al., where no significant difference has been observed between Neuro Patch® and autografts in terms of SSI. (20) Gaberel et al. (8) and Huang et al. (19) also showed that the use of Neuro-Patch® alone was not associated with the infection rate.

Several studies have highlighted the anti-adhesive properties of Neuro-Patch®, demonstrating its effectiveness in preventing adhesion to the cortical surface. Woo et al. (17) reported that in patients undergoing reoperation for glioblastoma, areas covered with subdurally placed Neuro-Patch® showed no meningo-cerebral adhesions, allowing safe reflection of the dura without cortical injury. Similarly, Wong et al. (18) and Jeong et al. (22) observed that Neuro-Patch®, when placed epidurally, maintained clear surgical planes and facilitated dissection without adherence to underlying neural tissues.

Out of the 23 product-specific publications, four described the application of Neuro-Patch® outside the intended use. The off-label use of Neuro-Patch® was identified in ophthalmological (5), cardiological (7, 23) and cranial nerve decompression surgery (16). However, these were either isolated clinical data or that the established treatment procedures have been exhausted and therefore alternative, off-label-use methods had to be used. In principle, no systematic off-label use of Neuro-Patch® was identified.

Altogether, the identified product literature does not negatively affect the benefit-risk ratio of Neuro-Patch®.

5.4 An overall summary of the clinical performance and safety

Safety and performance indicators which require support from relevant clinical data were defined and described in the clinical evaluation. The indicators depend on factors that can be either controlled by the manufacturer (e.g., material and manufacturing) or on situation-specific factors (e.g., surgical application, patient-specific factors), as well as on the surgical use and handling. Therefore, SOTA literature as well as clinical data from PMCF study, product-specific literature search, market feedback, review of the databases of regulatory authorities, product tests, sterility, usability, and biocompatibility assessment has been analyzed to assess the safety and performance of Neuro-Patch®.

For Neuro-Patch®, no safety/performance-related nor product-specific risks could be identified that do not comply with SOTA. As shown in Table 3, the specified acceptance criteria have been met for all device-relevant safety and performance outcome parameters.

No so far unknown risks or adverse events nor systematic off-label use associated with the use of the device have been identified in the presented data.

Table 3. Safety and performance parameters with specified acceptance criteria.

	Neuro-Patch® Clinical data from PMCF MiDura Study	SOTA acceptance criteria
Safety Parameter		
SSI	2.04%	≤ 2.1 + 1.4%
Meningitis	0.00%	≤ 4.5 + 4.6%
Performance Parameter		
CSF leak	2.72%	≤ 5.1 + 4.8%
PSMC*	0.34%	≤ 6.8 + 4.4%

* Pseudomeningocele

5.4.1 Clinical benefits for the patient

Neuro-Patch® is designed to provide an immediate, impermeable barrier to CSF, effectively preventing CSF leaks. Evidence from the ongoing PMCF MiDura study and product literature confirms its satisfactory performance in CSF leak prevention (see Tables 2 and 3). No systematic performance issues or safety concerns have been reported, supporting a high success rate consistent with its intended use.

As a non-absorbable implant, Neuro-Patch® is intended to remain in the body permanently unless removal is required due to surgical intervention or complications. It maintains structural integrity, mechanical strength, and resistance to resorption for at least 12 months—covering the critical period of dural healing, which typically completes within 3 to 12 months. Beyond this, the device no longer serves its primary function.

A six-year preclinical study in dogs showed no material degradation or changes in physicochemical properties, indicating minimal risk from long-term aging. Histology revealed early fibroblast infiltration and collagen synthesis within 3–6 weeks, neomembrane formation by 6 months, and complete, irritation-free integration by 12 months.

Clinical data from pre-CE and ongoing PMCF studies demonstrate safe and effective long-term use. Over 12 months, complication rates related to mechanical integrity or function—CSF leaks and PSMC—were below 3% and 1%, respectively, within accepted SOTA thresholds. CSF leaks possibly linked to Neuro-Patch® occurred in 1.42% of cases.

Overall, the data provide strong evidence of Neuro-Patch®'s clinical benefit and confirm its safety and performance for the intended use, meeting clinical expectations.

5.4.2 Benefits-risk assessment

When employed according to the intended purpose of the device, the product does not pose an unacceptable hazard regarding the clinical situation, the safety of patients or users. The indication, contraindications and intended use as well as warnings and precautions of Neuro-Patch® are clearly defined. The information materials supplied by the manufacturer are considered adequate.

The clinical risks connected to the device were demonstrated and evaluated in a clear way, the risk reduction measures are adequate, and the performance and safety can be proven by the presented data.
The available data for this clinical evaluation is deemed sufficient for a critical evaluation. Further measures to acquire post-market data concerning the safety and performance of the device, which will continuously and pro-actively provide data, are laid out in the PMCF-Plan, and are described in Section 5.5. *Ongoing or planned PMCF* of this SSCP.

According to the presented data, the clinical benefit overweighs the risks of the application of the Neuro-Patch®. The benefit-risk profile of the Neuro-Patch® is acceptable.

5.5 Ongoing or planned PMCF

No.#	PMCF measure	Aim of measure	Timeline
1	Market feedback / Complaints	Analyze reported production and device failures as well as difficulties in product handling.	Ongoing, yearly
2	FSN/FSCA/CAPA measures	Analyze reported production and device failures as well as difficulties in product handling, during routine clinical use.	Ongoing, yearly

3	Review of regulatory databases	Analyze reported failures concerning the device and equivalent or similar competitor devices	Ongoing, yearly
4	Clinical study *Multicentric, international, prospective, observational, study using Neuro-Patch® in duraplasty in neurosurgery:* **MiDura**	Safety and performance with focus on the occurrence of complications and usability.	Ongoing, single activity
5	Clinical data from literature	Safety and performance, monitoring of potential negative information	Ongoing, yearly

6 Possible diagnostic or therapeutic alternatives

In order to ensure a safe closure of the dura mater, the user can choose from various methods and materials. Primary closure of the dura mater as preferred treatment method is still valid. If this is not possible, dura mater defects can be treated satisfactorily with the help of replacement materials. The use of autologous tissues (e. g. fascia lata, temporal fascia) is primarily used here as they cause only minor foreign body reactions. The disadvantages of these are the limited availability with regard to the treatment of larger dura defects and the additional incision for harvesting the graft, which represents an additional risk of infection. Materials of animal origin are characterized by a low foreign body reaction. Furthermore, they are absorbed by the body over time and support cell proliferation and tissue regeneration. However, there is a theoretical risk of transmission of zoonoses (e. g. bovine spongiform encephalopathy) when using these materials. The use of absorbable or non-absorbable synthetic materials for dura replacement can reduce these risks, but complications such as foreign body reaction and limited tissue integration may also occur. Nonetheless, synthetic materials offer consistent quality and handling attributes, tunable physicochemical properties, and are readily available.

7 Suggested profile and training for users

Surgeons with required knowledge about the surgical technique and surgical training who are aware of the in vivo characteristics of the product, operating room personnel (set-up, handling, and functional check). No additional training is required.

8 Reference to any harmonised standards and CS applied

Standard / Guidance / Regulation	Date	Title	Product specific	Harmonized under MDR	Applied in full (F) or in part (P)
ANSI/AAMI ST72	2019	Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing	N	N	F
ASTM D 4169	2023	Standard Practice for Performance Testing of Shipping Containers and Systems	N	N	F
ASTM F88/F88M	2021	Standard Test Method for Seal Strength of Flexible Barrier Materials	N	N	F
DIN 58953-6	2023	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized	N	N	F

DIN EN 556-1	2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	N	N	F
DIN EN 62366-1 *VDE 0750-242-1*	2021	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)	N	N	F
DIN EN 868-5	2019	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	N	N	F
DIN EN ISO 10993-1	2021	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)	N	N	F
DIN EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	N	N	F
DIN EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	N	N	F
DIN EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	N	N	F
DIN EN ISO 10993-16	2018	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)	N	N	F
DIN EN ISO 10993-17	2024	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)	N	N	F
DIN EN ISO 10993-18	2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020 + Amd 1:2022)	N	N	F
DIN EN ISO 10993-2	2023	Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022)	N	N	F
DIN EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	N	N	F
DIN EN ISO 10993-3	2015	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	N	N	F
DIN EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	N	Y	F

DIN EN ISO 10993-6	2017	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)	N	N	F
DIN EN ISO 10993-7	2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008 + Cor 1:2009 + Amd 1:2019)	N	N	F
DIN EN ISO 10993-9	2022	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)	N	N	F
DIN EN ISO 11135	2020	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014 + Amd.1:2018)	N	N	F
DIN EN ISO 11138-2	2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	N	N	F
DIN EN ISO 11607-1	2024	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019 + Amd 1:2023)	N	N	F
DIN EN ISO 11607-2	2024	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019 + Amd 1:2023)	N	N	F
DIN EN ISO 11737-1	2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	N	N	F
DIN EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	N	N	F
DIN EN ISO 13485	2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	N	N	F
DIN EN ISO 14630	2013	Non-active surgical implants - General requirements (ISO 14630:2012)	Y	N	F
DIN EN ISO 14644-1	2016	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)	N	N	F
DIN EN ISO 14971	2022	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	N	N	F

DIN EN ISO 15223-1	2022	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	N	N	P
DIN EN ISO 20417	2022	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)	N	N	F
DIN ISO 2859-1	2014	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (ISO 2859-1:1999 + Cor. 1:2001 + Amd.1:2011)	N	N	F
ISO/TS 10993-20	2006	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	N	N	F
ISTA 3A	2018	Packaged – Products for Parcel Delivery System Shipment 70Kg (150 lbs) or Less	N	N	F
MDCG 2018-1	2021	Guidance on basic UDI-DI and changes to UDI-DI	N	n/a	F
MDCG 2019-8	2020	Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	N	n/a	F
MDCG 2019-9 Rev.1	2022	Summary of safety and clinical performance	N	n/a	F
MDCG 2020-5	2020	Guidance on Clinical Evaluation - Equivalence	N	n/a	n/a
MDCG 2020-6	2020	Guidance on Sufficient Clinical Evidence for Legacy Devices	N	n/a	F
MDCG 2020-7	2020	Guidance on PMCF Plan Template.	N	n/a	F
MDCG 2020-8	2020	Guidance on PMCF Evaluation Report Template.	N	n/a	F
MDCG 2021-11	2021	Guidance on Implant Card – Device types	N	n/a	F
MEDDEV 2.7/1/Rev.4	2016	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/eec and 90/385/eec	N	n/a	F

Part 2: Intended for patients

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay 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 to provide information on the safe use of the device.

List of abbreviation / glossary

Basic UDI-DI	Unique device identification device identifier
CSF	Cerebrospinal fluid
FSCA	Field safety corrective action
FSN	Field safety notice
MRI	Magnetic Resonance Imaging
PUR947	Polyester urethane
SSCP	Summary of Safety and Clinical Performance
SSI	Surgical site infection

1 Device identification and general information

1.1 Device trade name

Neuro-Patch®

Table 1. Neuro-Patch – Article list

Reference Number	Description	Content
1064002	Neuro-Patch® 12 cm x 14 cm	1 piece
1064010	Neuro-Patch® 6 cm x 14 cm	1 piece
1064020	Neuro-Patch® 8 cm x 9 cm	1 piece
1064029	Neuro-Patch® 6 cm x 8 cm	1 piece
1064037	Neuro-Patch® 4 cm x 10 cm	1 piece
1064040	Neuro-Patch® 5 cm x 6 cm	1 piece
1064110	Neuro-Patch® 4 cm x 5 cm	1 piece
1064122	Neuro-Patch® 2 cm x 10 cm	1 piece
1064123	Neuro-Patch® 1.5 cm x 3 cm	1 piece
1064045	Neuro-Patch® 4 cm x 5 cm	2 pieces
1064053	Neuro-Patch® 2 cm x 10 cm	2 pieces
1064061	Neuro-Patch® 1.5 cm x 3 cm	2 pieces

1.2 Manufacturer; name and address

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen/Germany

1.3 Basic UDI-DI

Basic UDI-DI[1] for Neuro-Patch®: 4039239000001401ZR

1.4 Year when the device was first CE-marked

Neuro-Patch® is CE marked[2] since 1996.

2 The intended purpose of the device, indications, contraindications and target populations

2.1 Intended purpose

Neuro-Patch® is used in neurosurgery as dura mater[3] replacement (further information can be found in Chapter *5.1 Clinical background of the device*).

[1] **Basic UDI-DI**: an identification number that is specific for a group of products with similar intended use
[2] **CE marking**: a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in the EEA.
[3] **Dura mater**: a membrane forming the outermost of the three coverings of the brain and spinal cord external.

2.2 Indication(s) and target population(s)

Indications

- For covering cerebral and cerebellar[4] dural defects
- For cerebral decompression surgery
- For covering spinal dural defects
- For spinal decompression surgery

Intended patient population

Regarding the intended target population, restrictions are defined by the contraindications.

2.3 Contraindications

Neuro-Patch should not be applied:

- In infected areas
- In open cerebrocranial traumata
- In open spina bifida[5]
- In case of known hypersensitivity against implant materials; for fixation materials please note the corresponding instructions for use
- In any application area that is not mentioned in "Indications"

3 Device description

3.1 Device description and material/substances in contact with patient tissues

Neuro-Patch® is a non-absorbable, fine fibrillar microporous membrane (Figure 1) made from high-purity, aliphatic[6] polyester urethane. The structure of Neuro-Patch® is characterized by open micropores which are aimed at facilitating the infiltration of fibroblasts[7].

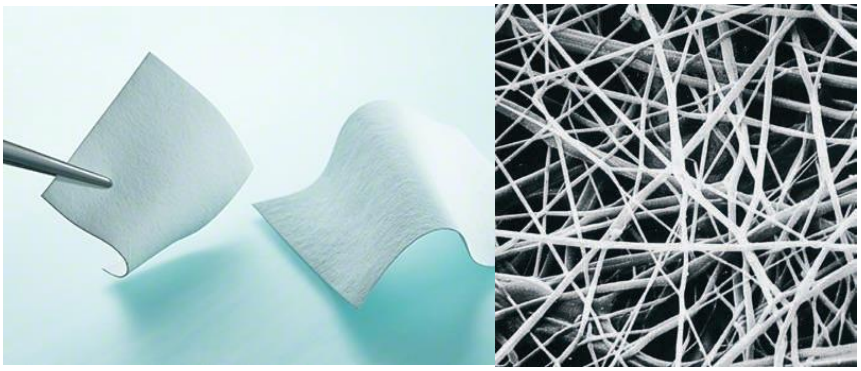

Figure 1. Product image (left) and microporous structure (right) of Neuro-Patch®.

[4] **Cerebral and Cerebellar**: both refer to parts of the brain, but they point to different regions, i.e., cerebral is the largest part of the brain, whereas cerebellar is located at the back of the brain, beneath the cerebrum (the largest part of the brain).
[5] **Spina bifida**: a birth defect where the spine and spinal cord don't form properly, potentially causing nerve and mobility issues.
[6] **Aliphatic**: refers to organic compounds composed of carbon and hydrogen atoms arranges in straight or branched chains.
[7] **Fibroblasts**: cells that produce collagen and other fibers, helping to form and repair connective tissue.

Neuro-Patch® is composed of a polyester urethane (PUR947) which is non-absorbable[8].

The product belongs to the group of neurosurgical implants.

- During the intended use, the following organs/tissue/body fluids come in contact with the device: brain, spinal cord, bone, dura mater, cerebrospinal fluid[9] (CSF) as well as blood.
- The application of the device is invasive.
- The application period of the device is long-term.
- The device is intended for clinical users: Surgeon with required knowledge about the surgical technique and surgical training who is aware of the in vivo characteristics of the product, operating room personnel (set-up, handling, and functional check).
- Neuro-Patch® is a single use device and will be delivered sterile (sterilization method: ethylene oxide).
- There are no restrictions regarding the intended patient population additional to the indications/contraindications.
- The device does not contain pharmaceutical components, animal or human tissue; is neither derived from blood products nor blood products themselves.
- The device is not radioactive.
- No changes have been made to the product since the market launch of Neuro-Patch®.

Operating principles and mode of action

Neuro-Patch® is used to restore a liquid-tight dural closure. Before implantation, Neuro-Patch® needs to be cut into the required shape based on the dural defect size. The implant must be sutured using non-degradable sutures. It is recommended to achieve tension-free embedding of the implant. Following implantation, the microporous structure of Neuro-Patch® (Figure 1) facilitates the infiltration of fibroblasts. These cells secrete collagen, contributing to the development of a thin neodural[10] membrane facilitating the integration of the implanted Neuro-Patch® with the surrounding native dura mater over time.

3.2 Information about medicinal substances in the device, if any

Neuro-Patch® doesn't contain any medicinal substances.

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

- Surgeon chooses implant size suitable for the closure of the defect.
- Neuro-Patch® will be cut into the desired shape based on the defect size.
- Neuro-Patch® will be fixed by continuous stitching using a non-absorbable suture material (polyester, polypropylene).
- The use of atraumatic round-bodied needles allows suturing without causing great damage to the implant.

[8] **Non-absorbable**: Non-absorbable material remains stable and retains in the human body for unlimited time.
[9] **Cerebrospinal fluid**: A colorless liquid that is secreted from the blood into the lateral chambers (ventricles) of the brain and serves chiefly to maintain uniform pressure within the brain and spinal cord.
[10] **Neodural membrane**: a newly formed membrane with characteristics similar to the dura mater.

- An additional seal with fibrin sealant[11] can be used.

3.4 Description of accessories, if any

Not applicable.

4 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

Potential risks have been identified and controlled according to *DIN EN ISO 14971 Medical devices - Application of risk management to medical devices.*

4.2 Remaining risks and undesirable effects

The general risks associated with surgery are assumed known and are therefore not described.
Within the scope of the legal obligation to provide information, reference is made to the typical risks, interactions and side effects listed below.

Possible risks, side effects and interactions of the application currently known to the manufacturer are:

- Cerebrospinal fluid (CSF) leak[12]
- Surgical site infection (SSI)
- Adhesion[13]
- Foreign body reaction (inflammation, granuloma[14], allergic reaction)

As presented in Table 2, the probability of the abovementioned risks occurring during the use of Neuro-Patch® is very low.

Table 2. Quantitative data on side effects.

Side effect	**Complaints data** (complaints/units sold over past 5 years)	**Clinical data – PMCF MiDura-Study** (294 patients)	Probability of occurrence*
CSF leak	0.004%	2.72%	Improbable** < 0.05%
SSI	0.002%	2.04%	Improbable < 0.05%
Adhesion	0.00%	0.00%	Improbable < 0.05%

[11] **Fibrin sealant**: a surgical glue made from blood proteins, used to stop bleeding and help tissues stick together during healing.
[12] **Cerebrospinal fluid leak:** escape of CSF from its normal space around the brain or spinal cord.
[13] **Adhesion** is a union of two surfaces that are normally separate.
[14] **Granuloma**: a cluster of immune cells, often formed as a response to infection or foreign body reaction.

Effective

Foreign body reaction	0.00%	0.00%	Improbable < 0.05%

* Considers weighted average of reported side effect derived from both Complaints data and Clinical data from the MiDura Study.
** The lowest medical occurrence according to the product risk analysis

4.3 Warnings and precautions

As per Instruction for Use

General safety information

To prevent damage caused by improper setup or operation, and to avoid compromising manufacturer warranty and liability:

- Use the product only according to this document.
- Follow the safety information in this document.
- Ensure that the product and its accessories are only operated and used by qualified personnel.
- Store any new or unused products in a dry, clean, and safe place.
- Keep this document accessible to the user.

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

Notes on surgical procedures

It is the user's responsibility to ensure that the surgical procedure is performed correctly. Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product.
Aesculap AG is not responsible for complications caused by:

- incorrect indication or implant selection
- incorrect surgical technique
- incorrect combination of implant components
- combination with components from other manufacturers not approved by Aesculap AG
- exceeding the limitations of the treatment method or non-observance of essential medical precautions

The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

MRI safety information

MRI examinations using magnetic fields of 1.5 or 3.0 tesla do not present an additional risk to implant bearers as the product is made of non-metallic material.

Sterility and storage

The product has been EO-sterilized (ethylene oxide) and is supplied in sterile packaging. The safe sterile provision of the product is only guaranteed if the sterile packaging is undamaged and unopened and the use-by date has not passed.

- Remove products from their original protective packaging only just prior to application
- Visually inspect the product packaging to ensure that the sterile barrier system is intact.
- Do not use products from open or damaged sterile packaging.
- Do not use the product after its use-by date.
- Do not reuse the product.
  The processing of the product affects its functionality. Risk of injury, illness or death due to soiling and/or impaired functionality of the product
- Do not reprocess the product.
- Store the product at 20 - 30°C.
- Store sterile packaged products in a dry, dark and temperature-controlled room that is protected against dust and do not expose them to extreme temperatures or ionizing radiation.
- Transport and handle products with care to prevent damage to the packaging and products.

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

When necessary, field safety corrective actions[15] (FSCAs) or field safety notifications[16] (FSNs) were issued regarding the products. For Neuro-Patch® neither FSCAs nor FSNs were required.

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

5.1 Clinical background of the device

Neuro-Patch® is used in neurosurgery as a replacement for the dura mater, which is the tough, outermost layer of the brain's protective covering, known collectively as the meninges. The meninges consist of three layers: the dura mater, the arachnoid, and the pia mater. Together, these layers form a protective envelope around the brain and spinal cord, known as the central nervous system.

One of the key roles of the meninges is to contain CSF - a clear, cushioning fluid that protects the brain and spinal cord from shocks and injury. CSF also helps regulate brain temperature and supports metabolic and chemical stability in the brain.

During neurosurgical procedures—such as the removal of brain tumors (like meningiomas or gliomas), craniectomy (a procedure in which part of the skull is removed), or surgeries for conditions like Chiari malformation[17] - surgeons often need to cut through the dura mater to access the brain. In some cases, the dura may be removed, shrink, or become damaged during the operation.

[15] **Field safety corrective actions**: are steps taken by a company to fix or reduce a safety problem with a medical device that is already being used out in the real world (hospitals or clinics).
[16] **Field safety notifications**: are official messages sent by a medical device company to inform users (like hospitals, doctors, or patients) about safety issue with a device that's already on the market.
[17] **Chiari Malformation**: a condition where part of the brain (the cerebellum) extends into the spinal canal, which can put pressure on the brain and spinal cord and disrupt the flow of spinal fluid.

Effective

When the dura cannot be closed directly by stitching (sutures), a dural substitute like Neuro-Patch® is used to restore the barrier. This is crucial to prevent CSF leaks, which can lead to serious complications. These include the accumulation of fluid under the surgical site (peridural CSF collection), the formation of abnormal fluid pathways (fistulas), or infections such as meningitis[18], cerebritis (inflammation of the brain tissue), or even brain abscesses.

5.2 The clinical evidence for the CE-marking

The CE marking of Neuro-Patch® is supported by laboratory testing, clinical studies, and real-world experience. Clinical evidence demonstrates that the device reliably prevents CSF leaks and integrates well with surrounding tissue after surgery.

In a clinical study involving 317 patients, Neuro-Patch® showed a 98% success rate in sealing CSF, with low complication rates. Long-term studies in animals have confirmed the material's stability over several years, with no signs of breakdown or harmful reactions.

Reports from healthcare professionals indicate that complaints are very rare, and no consistent safety concerns have been identified in practice. In addition to earlier clinical studies, the safety and performance of Neuro-Patch® continue to be monitored through an ongoing real-world follow-up study (MiDura study). This study confirms that the device remains safe and effective in everyday surgical use (see section 5.3 for details).

Overall, Neuro-Patch® is considered a safe, effective, and dependable dural substitute.

5.3 Safety

To ensure continued safety and performance of Neuro-Patch®, the manufacturer collects and reviews data from clinical use, scientific literature, and market feedback. So far, no consistent issues or complications related to Neuro-Patch® have been observed. Remaining potential risks are described in Chapter 4.2 of this SSCP. The benefit-risk profile of Neuro-Patch® is acceptable. Thus, the safety of the Neuro-Patch® is confirmed.

As part of this continuous monitoring, a clinical study called the MiDura Study was launched in 2019. This international, multi-center study followed 328 patients who received Neuro-Patch® during neurosurgery. The study aimed to assess how the product performs in real-life surgical settings.

The results showed a low rate of complications, including CSF leaks in 2.72% of cases, SSI in 2.04%.

All CSF leaks occurred in a brain region (posterior fossa) that is known to carry a higher risk due to pressure differences. Importantly, only seven serious complications were possibly linked to Neuro-Patch®. The observed CSF leak is very low and falls within the normal range of expected CSF leaks when compared to the literature.

Surgeons also rated the handling and ease of use of Neuro-Patch® very positively, with the majority rating it as excellent or very good.

These results support that Neuro-Patch® is safe and effective for its intended use in neurosurgery.

[18] **Meningitis**: an infection or inflammation of the protective layers around the brain and spinal cord, which can cause headaches, fever, and stiffness.

6 Possible diagnostic or therapeutic alternatives

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

6.1 General description of therapeutic alternatives

Different types of dural substitutes are available for surgeons to use when closing defects in the protective membrane (dura) around the brain or spinal cord. These options mainly differ by the material they are made from:

- Autografts (from the patient's own body, such as fascia lata or pericranium) are effective and have a low risk of immune reaction. However, harvesting this tissue requires a second surgical site, which may increase surgical time and recovery risk. Also, autografts may not be sufficient for large defects.
- Allografts (from human donors) and xenografts (from animals such as pigs or cows) are often easier to use and less invasive. However, allografts can carry a rare risk of disease transmission, such as Creutzfeldt-Jakob disease[19], though this is now highly controlled. Xenografts, typically processed into collagen-rich sheets, support natural healing but may trigger a mild immune response in some cases.
- Synthetic grafts, such as Neuro-Patch®, are made in controlled manufacturing environments and are always available. These non-absorbable materials offer high stability and consistency. While they are not absorbed by the body, they have shown very good results in clinical use.

Each material has specific benefits and limitations. The choice depends on the surgical situation, surgeon's preference, and patient condition.

7 Suggested training for users

Surgeons with required knowledge about the surgical technique and surgical training who are aware of the in vivo characteristics of the product, operating room personnel (set-up, handling, and functional check). No additional training is required.

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[19] **Creutzfeldt-Jakob disease**: a rare, fatal brain disorder caused by abnormal proteins called prions. It leads to rapid brain damage, memory loss, and loss of coordination.

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Signatures

This document is signed electronically (see last page).

Revision history

No.	Type of Revision	Date	Revision validated by the Notified Body
1	Initial preparation of the SSCP	24.06.2020	Validation language: English
2	Update of the SSCP according to the Feedback of the Notified Body (MDR_IVDR Request for Additional Information and Deficiency Report Clinical No. 1; Order no: 713197662; Dated: 2020-12-28)	11.03.2021	Validation language: English
3	Update of the SSCP according to the Feedback of the Notified Body (MDR_IVDR Request for Additional Information and Deficiency Report Clinical No. 2; Order no: 713197662; Dated: 2021-03-19)	12.04.2021	Validation language: English
4	Missing document history of Rev. 3 included	21.05.2021	Validation language: English
5	Update according to the minor update 2021 of the CER: Part 1 – Chapter 5.3 Literature on the product: Addition of two newly identified product specific publications. Part 1 – Chapter 5.5 MiDURA-Study: Information updated to the current state of the study.	15.07.2021	Validation language: English
6	Update of the SSCP according to the Final Technical Report of the Notified Body (see Report number: 713197662). - Update of the SRN - Update of chapter *8 Reference to any harmonised standards and CS applied*	28.09.2021	Not yet validated by the NB
7	Update to the current document format. Update according to the regular update 2023 of the CER: Part 1 – Chapter 5.5 MiDURA-Study: Information updated to the current state of the study. Update of Chapter 3 to warrant consistency across interlinked documents.	17.01.2024	Not yet validated by the NB
8	Complete revision in the context of re-certification	25.05.2025	Not yet validated by the NB
9	• Document history of Rev. 1-7 included. • Description of the main changes in Rev. 8 included: - Section 4.2: addition of Table 4 with the quantitative data on side effects as per MDCG 2019-9 Rev 1. - Part 1 Section 5.3: Literature on the product has been rewritten and updated with recent publications evaluated in CER.	See "Effective Date" on approved document	Not yet validated by the NB

	- Part 1 Section 5.4: addition of Sections 5.4.1 Clinical Benefit and 5.4.2 Benefit-risk assessment as per MDCG 2019-9 Rev 1. - Chapter 7: Clinical user revised to align with the wording in the IFU, CER, and PMCF Plan. - Part 1 Chapter 8: List of harmonized standards and CS applied has been revised to align with the source document - List of Applied Standard Rev. 10, BDoCS-AIM-015919 (change to information on MDR Article 32.2e). No changes to information on MDR Article 32.2a and c have been made.		
10	Version 9.0 validated by the Notified Body (Validation Statement from 01.10.2025, BDoCS-AIM-172746)	See "Effective Date" on approved document	Validated by the NB Validation language: English

Title: SSCP_Neuro-Patch Initiator: Izabela ? Firkowska-Boden

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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Meaning: Approve Document
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