APPROVAL INFORMATION

BRAINLAB
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SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

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- Clinical Evaluation Documentation Author
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Change Log

Enter date	Enter change description
Enter date	Enter change description
October 2021	Updated clinical information section (aligned with CEP, CER and DD); updated references to CER; added Change Log and References section

DISPOSABLE STYLET

TABLE OF CONTENTS

1 PURPOSE

This Summary of Safety and Clinical Performance (SSCP) is following MDCG 2019-9 “Summary of safety and clinical performance - A guide for manufacturers and notified bodies” and 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.

2 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Device Name	Disposable Stylet
Article number (s)	- 55797 Disposable Stylet, 10 pcs (of 55793) - 55793 Disposable Stylet, 1pc (no quote item)
Basic UDI-DI	4056481DisposableStyletAC
Manufacturer	Brainlab AG Olof-Palme-Str. 9 81829 München Germany
Manufacturing site (s)	- Inpac Medizintechnik GmbH (short: Inpac) o general contractor and packaging supplier o Address: Neureutstraße 4 / Gewerbestraße 34, 75217 Birkenfeld - Gebr. Renggli AG (short: Renggli) o Manufacturing supplier o Address: Schweizerbildstraße 57, 8200 Schaffhausen, Switzerland - Injecta GmbH (short: Injecta) o Needle supplier o Address: Neue Wiesen 1-5, 08248 Klingenthal, Germany - Sterigenics Germany GmbH (short: Sterigenics) o Sterilization supplier o Address: Kasteler Str. 45, 65203 Wiesbaden, Germany
SRN	DE-MF-000006183
Medical device description nomenclature	- GMDN**:** 63571 (Intracranial catheter navigation optical stylet) - EMDN: Z12100685 (stereotactic neurosurgery instruments – consumables) - MDN 1203 (Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools - MDS 1005 (Devices in sterile condition) - MDT 2001 (Devices manufactured using metal processing - MDT 2002 (Devices manufactured using plastic processing - MDT 2008 (Devices manufactured in clean rooms and associated controlled environments) - MDT 2011 (Devices which require packaging, including labelling
Class of device	Class III, Rule 6
Year of first certificate issued for the device	December 2009

Name and Single Identification Number of Notified Body	TÜV Sued Product Service GmbH Ridlerstrasse 65 80339 München SIN: 0123

3 DEVICE DESCRIPTION

The Disposable Stylet is a pre-calibrated guiding stylet for optically tracked navigated placement of catheters/ shunts in neurosurgery and is an accessory of the Cranial IGS system. It may also be used for free handed placement. A compatible third-party ventricular catheter, which is to be used with the Disposable Stylet, is indicated for the drainage of cerebrospinal fluid (CSF) and other fluids of similar physical properties in order to reduce and control increased intracranial pressure (ICP) temporarily.

This invasive device is delivered sterile and is intended for single transient use (< 60 min) on an individual patient during a single procedure.

The only component in direct contact with patients is the guide wire of the Disposable Stylet. The guide wire is composed of 304V (1.4301) stainless steel and has direct patient contact to CNS/CSF.

The device is available as a dispenser box (55797) of 10 packed and sterilized Stylets (55793). Former single packaging configuration 55798 (1pc of 55793) is not available for customer sales anymore, it was last sold in 2018.

Overall size: 260 x 50 x 10 mm
Guide wire dimensions:

- Free length: 165 mm
- Outer diameter: ∎ 1.1 mm

Method of sterilization: Ethylene oxide sterilization, SAL 10^{-6}

Operating principle:

The device is used in conjunction with a ventricular catheter or shunt supplied by third party and a Brainlab cranial IGS system. The stylet is inserted into the lumen of a ventricular catheter or shunt enabling image-guided placement to a predefined target. Used technology: infrared passive tracking technology The Disposable Stylet is a pre-calibrated instrument. This means that the software contains calibration information optimized for the Disposable Stylet. Further calibration by the user is not necessary. Marker disks geometry of Disposable Stylet is detected by infrared cameras and position of Disposable Stylet is displayed on navigation screen in relation to registered patient's anatomy.

Compatible shunts/catheters must fulfill all of the following criteria:

- Inner diameter: between 1.3 mm and 1.5 mm
- Length: ≤ 150 mm
- Materials: Silicone or Polyurethane (PU), either uncoated or coated with barium or silver

Compatible Brainlab Software (navigation and planning software):

- Cranial 2.1
- Cranial 3.0
- Cranial 3.1

3.1 INTENDED USE, INDICATIONS FOR USE, INTENDED PURPOSE

3.1.1 Intended Purpose

The Disposable Stylet enables the placement of catheters / shunts in neurosurgery.

3.1.2 Intended Use

The Disposable Stylet is a pre-calibrated guiding stylet for optically tracked navigated placement of catheters / shunts in neurosurgery. It may also be used for freehanded placement of catheters / shunts.

3.1.3 Indications for Use

The surgical procedures for navigated intracranial catheter placement include indications where the insertion of a draining catheter, e.g. EVD, shunt or Ommaya reservoir is required.

3.2 CONTRAINDICATIONS

Contraindications (like e.g. insufficient hemostasis) and side effects (bleeding, infection, malfunction of shunt systems) are procedure intrinsic and/or catheter/shunt system related and not specific for the use of the Disposable Stylet.

There are no known additional contraindications specifically for the Disposable Stylet.

3.3 INTENDED PATIENT POPULATION

There are no gender, age or ethnic limitations on patient population for the use of Disposable Stylet when used within its intended use.

3.4 RISKS/WARNINGS/SIDE EFFECTS

For clinical use of the Cranial IGS system the following side effects may apply in general, however, they are not specifically related to the Disposable Stylet:

- Extended intervention time in certain cases due to additional time for setup and patient registration.
- In certain cases additional incisions to the patients skin/bone are made for registration purposes and attachment of a skull fixated reference array.

Side effects associated with shunt catheter placement (independent from the Disposable Stylet itself) are:

- Overdrainage
- Subdural fluid collection

Adverse events / complications:

Adverse events / complications that may result from the use of Disposable Stylet include those associated with medications, materials and methods utilized in the surgical procedure, as well as the patient's degree of tolerance to any foreign object temporarily inserted in the brain. However, these complications may in general occur for any neurosurgical intervention and are independent from the device itself.

Adverse events / complications which are directly associated with the Disposable Stylet are:

- Failure in accuracy
- Mechanical failures
- Potential intolerance of device materials

Potential adverse events associated with shunt catheter placement (independent from the Disposable Stylet itself):

- Hemorrhage
- Infection
- Shunt migration
- Hematoma with neurological compromise
- Development of abdominal pseudocyst (strictly associated with peritoneal catheter)

Warnings and Cautions as listed in the instructions for use of the Disposable Stylet:

Cautions:

- The Disposable Stylet is a highly sensitive medical device. Handle it with extreme care.

Warnings:

- The Disposable Stylet is delivered sterile. If any of the sterile components come into contact with an unsterile environment during unpacking or clinical use, dispose of the stylet immediately.
- Verify the sterile packaging prior to opening that it is not damaged. Visually inspect for breaches in the sterile barrier system integrity prior to use. If the sterile packaging is damaged, do not use the Disposable Stylet.
- Verify prior to opening the sterile packaging that the expiration date has not lapsed. If the expiration date has lapsed, do not use the Disposable Stylet.
- Verify that the Disposable Stylet is not bent before using it or inserting into the shunt/catheter.
- Do not bend the Disposable Stylet and do not try to straighten a bent stylet. Dispose of bent or damaged stylet.

- Do not cut the Disposable Stylet shorter.
- Make sure to avoid bending the Disposable Stylet when inserting it into the shunt/catheter.
- Only use the Disposable Stylet with shunts/catheters that have closed ends and that are designated for use in the intended application.
- Verify prior to use that the Disposable Stylet slides easily (without sticking) in and out of the shunt/catheter.
- Only the steel part of the Disposable Stylet may be used invasively. No other part of the stylet should come into patient contact!
- Do not cover the reflective disks on the Disposable Stylet with your hand while it is being navigated.
- Do not use the Disposable Stylet if the reflective disks of the Disposable Stylet are soiled, wet or contaminated with blood. This will result in inaccurate navigation.
- The Disposable Stylet is designed for single use only and must not be reprocessed. Reprocessing damages the reflective discs. This will lead to inaccurate navigation, which could result in serious patient injury.
- Make sure the insertion is straight. Never bend the Disposable Stylet or adjust the trajectory once you begin insertion.

Residual risks:

No other significant residual risks beside those listed in side effects, complications and adverse events exist.

Following table summarizes and quantifies all identified and mitigated risks related with the Disposable Stylet as defined in the risk analysis.

Risk (harm and hazardous situation)	**Probability after measures**
Hazard: Wrong materials or manufacturing process residues Hazardous situation: Leachables or extractables from materials or manufacturing process aids, on components of Disposable Stylet with direct patient contact, are non-biocompatible for its intended use. Harm: Cytotoxic reaction, sensitization, irritation and intracutaneous reactivity, or systematic acute toxicity	< 0.1%
Hazard: Ethylene Oxide Hazardous situation: Residues of ethylene oxide remain on device or within sterile packaging in toxic concentrations after EO sterilization process. Harm: Cytotoxic reaction, sensitization, irritation and intracutaneous reactivity	< 0.001%
Hazard: Endotoxins Hazardous situation: Endotoxins on Disposable Stylet get in contact with patient brain during use. Harm: Pyrogenic reaction.	< 0.1%
Hazard: Sharp edges Hazardous situation: The user holds the Disposable Stylet in hands during installation, clinical procedure and dismantling. Harm: The user cuts itself or puncture its skin with sharp edges of the Disposable Stylet.	< 0.001%
Hazard: Wrongly placed catheter	< 0.1%

Hazardous situation: The catheter is placed too shallow or too deep because the tip of catheter is not aligned with the tip of the Stylet. The distal part of catheter doesn´t reach the intended position. Harm: Damage of critical structure (e.g. more brain tissue is harmed / punctured than intended.	
Hazard: Inaccurate navigation Hazardous situation: The tracking of the Disposable Stylet is not accurate. The pre-calibrated Stylet is placed in position different than intended. Harm: Damage of critical structures (e.g. punctuation of important brain regions, blood vessels or nerve pathways.)	< 0.1%
Hazard: Device contamination Hazardous situation: The device is contaminated and / or not sterile and used for surgery. Harm: Patient infection or inflammation.	< 0.1%
Hazard: Damaged product Hazardous situation: The device is damaged or its intended performance is degraded due to sterilization process, transport or shelf life aging. Harm: Patient injury due to device failures.	< 0.1%
Hazard: Aseptic handling or unintended use Hazardous situation: Packaging does not allow aseptic handling of the device. Device is reprocessed and reused, and thus sterility or performance are no longer ensured. Device is wrongly disposed of. Harm: Patient or user infection or inflammation, or patient injury due to device failure.	< 0.1%

Considering the clinical benefit when using the Disposable Stylet, all risks identified for the device are acceptable when weighed against the intended benefits of the device. The overall residual risk of the device is acceptable.

4 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

4.1 EVALUATION BASED ON EQUIVALENCE

N/A

4.2 DATA FROM CLINICAL INVESTIGATIONS

N/A

4.3 OTHER CLINICAL DATA

Clinical data for the Disposable Stylet has been gathered through post-market surveillance and post-market clinical follow-up activities.

Device literature searches and incident searches within the external databases MAUDE and BfArM as well as of the Brainlab complaint database were performed for the release and subsequent annual PMS reviews. Furthermore, a post-market survey was conducted since 2016 in order to obtain clinical data for the Disposable Stylet

Clinical data from literature:

The following pertinent literature has been identified through literature searches:

1. **(Bailey et al. 2013)**
   Overall relevance: fair | Methodological quality: low | Level of clinical evidence: low (Level V)
   Outcome:
   Catheter placement methods: freehand, optical navigation
   Catheter placement accuracy: freehand: good position in 33% (= grade 1), acceptable position in 56% and poor position in 11% of the patients | optical navigation: good position in 75%, acceptable position in 19%, poor position in 6%
   Complications: no information
   Contribution to clinical evaluation:
   Using a pre-calibrated catheter placement tool increases the accuracy of catheter placements for children challenging intra-cranial targets. Claims on clinical performance and safety are supported.

2. **(Feulner et al. 2018)**
   Overall relevance: fair | Methodological quality: low | Level of clinical evidence: low (Level V)
   Outcome:
   Catheter placement methods: optical navigation
   Catheter placement accuracy: grade 1 (acc. to Yim et al) in 100%
   Complications: n/a, cadaver study
   Contribution to clinical evaluation:
   Method of FDCT imaging in combination with the optical Brainlab Disposable Stylet is fast, accurate, and easy to use. Ideal positioning (grade 1) of the catheter tip in all cases was confirmed by post-procedural imaging. Image-guided catheter placement represents a viable tool to lower rates of misplacement. EVDs can be placed with high precision using the BrainLAB reference headband in combination with the precalibrated disposable stylet for neuronavigated catheter insertion without rigid fixation of patient head. Claims on clinical performance are supported.

3. **(Halliday and Kamaly 2016)**
   Overall relevance: minor | Methodological quality: low | Level of clinical evidence: low (Level V)
   Outcome:

Catheter placement methods: optical navigation
Catheter placement accuracy: n/a, successful case
Complications: no information
Contribution to clinical evaluation:
Sufficient accuracy was achieved by the use of the Disposable Stylet even for described "off-label use" for navigation of peel-away catheter.

4. **(Keric et al. 2013)**
Overall relevance: compelling | Methodological quality: medium | Level of clinical evidence: medium (Level IV)
Outcome:
Catheter placement methods: optical navigation
Catheter placement accuracy: in ICU: optimal position in 100%, in OR: optimal position in 81.8%
Complications: in ICU: 10% hemorrhage, in OR: 9.1% infection, 11.1% bleeding
Contribution to clinical evaluation:
Using the Disposable Stylet is a straight forward and safe procedure for image-guided catheter placement in the ICU. Successful image-guided placement of intracranial catheters such as EVDs or catheter for lysis therapy for ICH could be achieved. The Disposable Stylet is precalibrated and recognized by the Brainlab image-guidance system. As alternative to fixation in a head clamp, the Disposable Stylet can be used in conjunction with a Brainlab headband for short interventions and for patients in critical conditions. Claims on clinical performance and safety are supported.

5. **(Malinova et al. 2014)**
Overall relevance: strong | Methodological quality: medium | Level of clinical evidence: medium (Level IV)
Outcome:
Catheter placement methods: pointer-guided, optical navigation (stylet)
Catheter placement accuracy: pointer-guided / stylet: 1.2% / 0% central catheter position, 54% / 87% nearly parallel to the greatest diameter but with deviation from the center, 14.8% / 0% partially intrahematomal catheter position, 20% / 11% position at the edge of the hematoma, 10% / 2% outside of the hematoma
Complications: no information
Contribution to clinical evaluation:
The preregistered stylet facilitates a satisfactory intra-hematomal catheter placement in patients with spontaneous ICH and is a viable alternative to frameless stereotaxy and guidance with the articulated arm. Claims on clinical performance and safety are supported.

6. **(Yim et al. 2016)**
Overall relevance: strong | Methodological quality: medium | Level of clinical evidence: low (Level V)
Outcome:
Catheter placement methods: iCT, neuronavigation
Catheter placement accuracy: iCT: grade 1 in 96%, / neuronavigation: grade 1 in 88%
Complications: neuronavigation: 3.1% hemorrhage, 3.1% return to operating room
Contribution to clinical evaluation:
Similar accuracies for catheter placements using neuroendoscopy and frameless stereotaxy. Reported disadvantages of frameless stereotaxy: increased time in operating room, additional costs for disposable parts of navigation system and needed use of head fixation.

> Nevertheless, the study supports the claims on clinical safety since no shunt infections occurred as well as the claims on clinical performance. Catheter placements could be successfully performed using the precalibrated Disposable Stylet.

During latest PMS review cycle a planned clinical trial comparing intraoperative ultrasound guided to stereotactic navigated ventriculoperitoneal shunt placement has been identified. (Leu and Mariani 2020) In 2021 the study protocol has been published by (Leu et al. 2021). There are no study results available yet, the study completion is estimated to be in October 2022. Nevertheless, this study will be highly relevant since the Disposable Stylet and the Brainlab system will be used for the navigated procedures. The study aims to provide class I evidence for the best possible surgical technique of the frequent surgery of VPS placements. Primary outcome will be the surgical intervention time. Secondary outcome will be the accuracy of catheter positioning, VPS dysfunction and need for revision surgery, total operation and anaesthesia times, and amount of intraoperative ventricular puncture attempts as well as complications, any morbidity and mortality.

Clinical data from incident searches:

A pro-active search for issues and incidents reported to external authorities and filed in Brainlab internal databases has been performed on a yearly basis, overall covering the search period from 01 Jun 2010.

In summary, no records were found describing incidents related to the Disposable Stylet according to the defined search criteria causing patient injury that would have to be reported.
Reviewing the internal complaint database, the review cycles revealed only a small number of complaints, mainly based on wrong usage of the device in combination with the navigation system (16 in total) and failed gluing connection of stylet within handle (total 6). The other complaint categories (total 7) are not safety relevant and thus are not further considered for risk analysis. Considering the sales quantities of the device, the risk of a failed gluing connection with an overall complaint rate of 0.012% is rated as improbable and an acceptable isolated case.

Clinical data from user survey:

As part of the annual post-market surveillance activities for the Disposable Stylet under MDD a post-market clinical follow-up survey has been introduced in 2016 in order to pro-actively collect customer feedback on the Disposable Stylet in combination with the Brainlab cranial image-guided surgery systems. The survey questions have been expanded over the years to gather additional feedback on the user experience, procedures performed, and patient profile in addition to device performance as well as to address procedure related safety information.

The survey shows that the Disposable Stylet is routinely used for all indications, some surgeons use it especially in challenging indications. 43% of the contacted customers use the device in pediatric procedures. Compared to non-challenging indications, 60% of the customers rated the value of the Disposable Stylet as significantly higher, 40% as higher. In comparison with freehand procedures in challenging indications, 80% of the customers rated the use of the Disposable Stylet as significantly better (15% as better, 5% as equal) in terms of successful catheter placement.

Overall, the collected data are sufficient to prove the clinical safety and performance of the Disposable Stylet and to confirm its intended use within the target patient population incl. pediatrics.

4.4 SUMMARY ON SAFETY AND PERFORMANCE AND BENFIT/RISK CONCLUSION

The Disposable Stylet is a pre-calibrated guiding stylet for optically tracked navigated placement of catheters / shunts in neurosurgery.

Optical tracking with the use of cameras to localize visual markers as is used in the Brainlab Cranial IGS navigation system together with the Disposable Stylet, is a well-established tracking modality. From a technical, biological and clinical point of view, the overall residual risk (for quantification please refer to 3.4) for the clinical use of the product under evaluation is acceptable after implementation of risk-mitigating measures.

The reported complication rates for procedures with the Disposable Stylet were comparable to the complication rates identified in the state of the art. Therefore, the claim on clinical safety can be successfully supported.

The reported clinical data in the appraised and analyzed scientific literature demonstrate the successful clinical use of the Disposable Stylet for the intended use and purpose, the indications for use and the intended patient population. The decisive performance parameter, the success rate of catheter insertion into the brain with the guidance of the Disposable Stylet, is comparable or better when compared to success rates reported in the state of the art for similar or alternative methods of catheter insertion.

In summary, based on the pertinent literature identified and supported by post-market surveillance data the Disposable Stylet enables an acceptable catheter position sufficient for its intended use within the entire target patient population and can be considered safe and effective for clinical use.

The remaining risks have to be considered as of minor clinical significance compared to the overall benefit for the patient.

Regarding biocompatibility and sterility, all performed tests meet the requirements of current applicable versions of ISO 10993-1, ISO 10993-7, ISO 14971, and MDR 2017/745 for a device with limited contact duration (<24 hours) and the Disposable Stylet can be considered safe and suitable for use as directed.

The benefit/risk ratio of the use of the Disposable Stylet is regarded as positive, when at least moderate benefit for the patient has to be held out by the responsible physician. The latter can be expected in patients with hydrocephalus and increased intracranial pressure.

4.5 PLANNED OR ONGOING PMCF

A systematic review of clinical data derived from internal (product feedback and complaints, survey among users) and external (such as device registries and literature) sources is performed on a yearly basis.

Based on a long established history of clinical use since initial release of the Disposable Stylet in December 2009 demonstrating its safety and effectiveness for the intended use and purpose, the indications for use and the intended patient population, the primary objectives of PMS and PMCF are to confirm that the safety and effectiveness of the device are still ensured. There are no unanswered

questions relating to the use of the Disposable Stylet. In addition, there are no unconsidered risks, complications or unexpected device failures that would require further investigation. Based on PMS / PMCF data over such a long period it is also not expected that any unconsidered risks will be identified with further PMCF activities.

The rating and acceptability of any risks that remain after risk mitigation shall be reassessed on a basis of a larger population of patients and clinical users and thus of a factual evidence, and unknown or emerging risks shall be identified.

5 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Available medical options for ventricular catheter placement are the freehand technique, ultra-sound-guided placement, fluoroscopic-guided placement, endoscopic-assisted placement, smartphone-assisted placement, robotic guided placement, electromagnetic and optically navigated placement.

The most common clinical indication is therapy of hydrocephalus and management of intracranial pressure (ICP).

It can be concluded that the suitability of a specific medical option for the (guided) insertion of an intracranial catheter mostly depends on the target location of the catheter and respective requirement on accuracy. It can be concluded that the deeper the insertion of the stylet and the more eloquent the target region and the smaller the lesion the higher the accuracy shall be. Available data show that the accuracy of market-available stylets is sufficient for the intended use cases to achieve correct catheter positions for the treatment of hydrocephalus or increased intracranial pressure.

In summary, clinical effectiveness and benefits of optically tracked stylets are proven in comparison to their potential related complications or risks based on long established history of clinical use.

Considering the product description and the available documentation, it can be stated that the Disposable Stylet is a state-of-the-art device, as nowadays in clinical routine use.

6 SUGGESTED PROFILE AND TRAINING FOR USERS

The Disposable Stylet is used by Neurosurgeons. No specific training is needed for users familiar with optical IGS systems. For users non-familiar with optical IGS systems a training on using Brainlab optical IGS systems is recommended.

7 REFERENCE TO ANY HARMONIZED STANDARDS AND CS APPLIED

Standard / Guideline or CS applied	Year/ revision of the standard/guideline/CS	Applied full or in part
EN ISO 13485	2016/AC:2018	full
EN ISO 14971	2019	full
EN 1041	2008+A1:2013	full
EN ISO 15223-1	2021*	full
ISO 20417	2021	full

EN 62366-1	2015	full
ISO 10993-1	2018	full
ISO 10993-4	2017	full
EN ISO 10993-5	2009	full
EN ISO 10993-7	2008 AMD 1:2019	full
EN ISO 10993-17	2009	full
EN ISO 10993-18	2020	full
ISO 7153-1	2016	full
AAMI TIR28	2016	full
EN ISO 11135	2020	full
EN ISO 11737-1	2018	full
EN ISO 11737-2	2020	full
EN ISO 11607-1	2020	full
EN ISO 11607-2	2020	full
EN ISO 7153-1	2017-02	full
Regulation (EC) No 1907/2006	2006	full
ASTM F1980	2016	full
ASTM D4169	2016	full
MDCG 2019-9	2018	full
MEDDEV 2.7-1 Rev.4	2016	full

* Harmonized according to Summary of references of harmonized standards published in the Official Journal – Regulation (EU)

8 REVISION HISTORY

SSCP revision number	Date issued	Change description	Revision validated by NB
001	11-08-2021	First issue according MDR 2017/745	☒ yes Validation language: English ☐ no

9 PUBLICATION BIBLIOGRAPHY

Bailey et al. (2013): Brainlab optical image guided pre-calibrated catheter placement stylet. Our early experience versus standard stylet registration.

Feulner, Julian; Lang, Stefan; Buder, Thomas; Struffert, Tobias; Buchfelder, Michael; Brandner, Sebastian (2018): Flat Panel Detector Computed Tomography-Guided Placement of External Ventricular Drains Using the BrainLAB Headband and Precalibrated Disposable Stylet Instrument: A Cadaveric Feasibility Study. In *World neurosurgery* 115, pp. 324–328. DOI: 10.1016/j.wneu.2018.04.192.

Halliday, Jane; Kamaly, Ian (2016): Use of the Brainlab Disposable Stylet for endoscope and peel-away navigation. In *Acta Neurochir* 158 (12), pp. 2327–2331. DOI: 10.1007/s00701-016-2981-3.

Keric, Naureen; Neulen, Axel; Kantelhardt, Sven Rainer; Giese, Alf (2013): Image-guided implantation of pre-calibrated catheters in the ICU: a feasibility study. In *Acta Neurochir* 155 (9), pp. 1781–1786. DOI: 10.1007/s00701-013-1789-7.

Leu, Severina; Halbeisen, Florian; Mariani, Luigi; Soleman, Jehuda (2021): Intraoperative ultrasound-guided compared to stereotactic navigated ventriculoperitoneal shunt placement: study protocol for a randomised controlled study. In *Trials* 22 (1), p. 350. DOI: 10.1186/s13063-021-05306-5.

Leu, Severina; Mariani, Luigi (2020): Intraoperative Ultrasound Guided Compared to Stereotactic Navigated Ventriculoperitoneal Shunt Placement: A Randomized Controlled Study. University Hospital of Basel, Department of Neurosurgery. Available online at https://clinicaltrials.gov/ct2/show/NCT04450797?term=Brainlab+OR+Stylet&cond=hydrocephalus+OR+%28ICP+%28Intracranial+Pressure%29%29+OR+%28Intracerebral+Hemorrhage%29+OR+%28Drainage%2C+Cerebrospinal+Fluid%29&draw=1&rank=1, checked on 8/3/2020.

Malinova, Vesna; Stockhammer, Florian; Atangana, Etienne Ndzie; Mielke, Dorothee; Rohde, Veit (2014): Catheter placement for lysis of spontaneous intracerebral hematomas: is a navigated stylet better than pointer-guided frameless stereotaxy for intrahematomal catheter positioning? In *Translational stroke research* 5 (3), pp. 407–414. DOI: 10.1007/s12975-014-0326-1.

Yim, Benjamin; Reid Gooch, M.; Dalfino, John C.; Adamo, Matthew A.; Kenning, Tyler J. (2016): Optimizing ventriculoperitoneal shunt placement in the treatment of idiopathic intracranial hypertension: an analysis of neuroendoscopy, frameless stereotaxy, and intraoperative CT. In *Neurosurgical focus* 40 (3), E12. DOI: 10.3171/2015.12.FOCUS15583.