

Bypass using Endovascular Transvenous Cerebrospinal Fluid Shunt

September 2026 ICD-10 Coordination and Maintenance
Committee Update

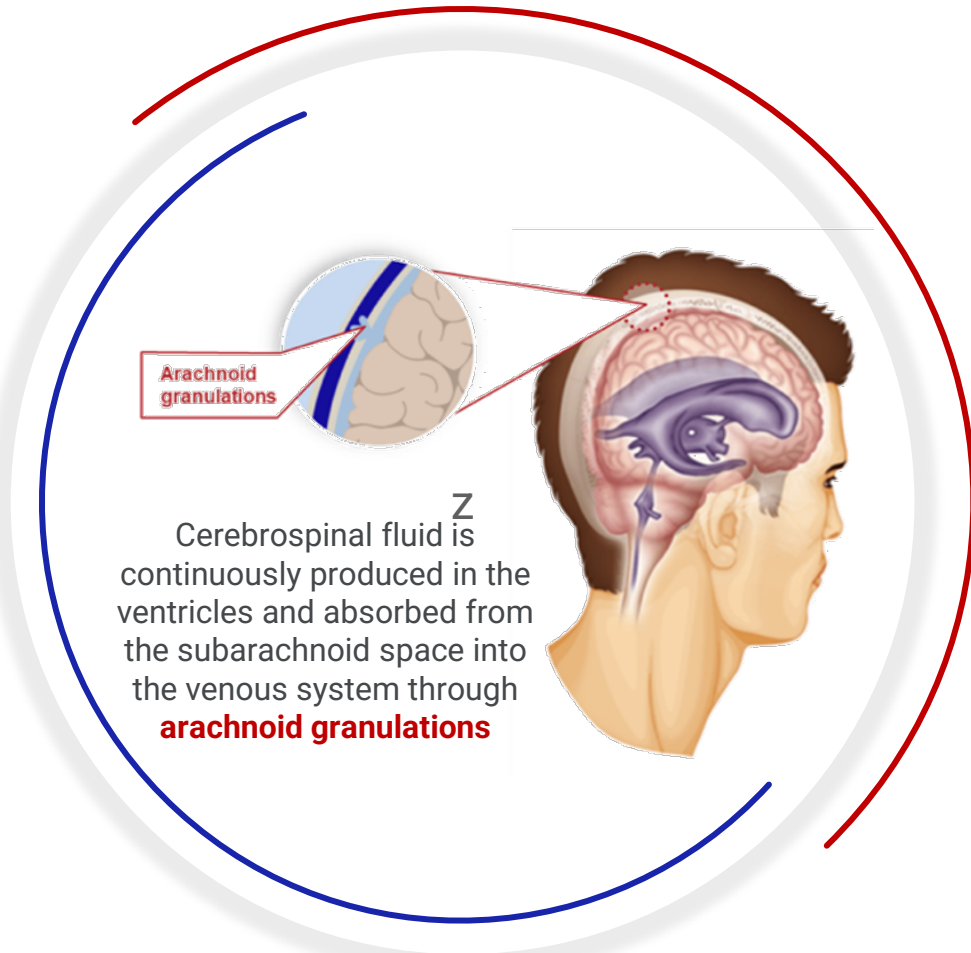


Topics

- **Disease State: Hydrocephalus**
- **Current treatment procedure: Ventriculo-peritoneal (VP) shunt**
- **Bypass using Endovascular Transvenous Cerebrospinal Fluid Shunt**
- **eShunt[®] System Clinical Evidence**



Hydrocephalus Background



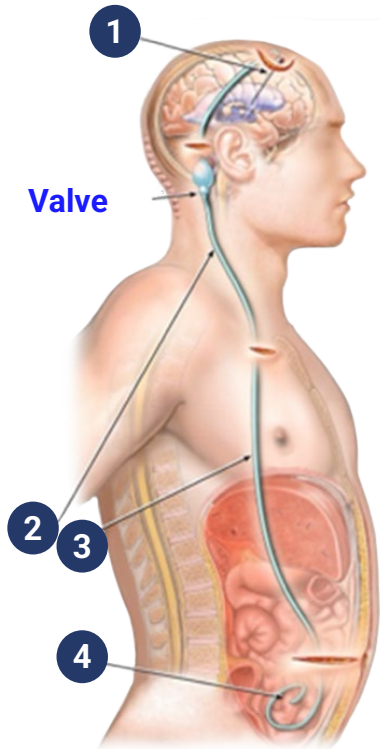
Cerebrospinal fluid (CSF) provides cushioning, cellular nutrients and metabolic waste product elimination pathway.

CSF is produced at a rate of about 0.2 to 0.7 mL per minute, totaling around 500-600 mL (or more) daily, constantly replenishing the body's ~150 mL total volume, meaning the entire CSF volume is turned over roughly 3-4 times a day.¹

Hydrocephalus is a chronic, neurological condition caused by abnormal accumulation of cerebrospinal fluid within the cavities of the brain.



Traditional Approach for Hydrocephalus: VP Shunt



- 1 Ventricular catheter placed in lateral brain ventricle via burr hole drilled in skull
- 2 Catheter connected to valve placed under skin
- 3 Distal tubing tunneled under the skin
- 4 VP shunt provides conduit for excess CSF to flow from ventricle to peritoneal cavity

Current treatment results in frequent complications and high failure rates



Conventional Shunt Complication / Failure: 40% @ 1 year >50% @ 2 years

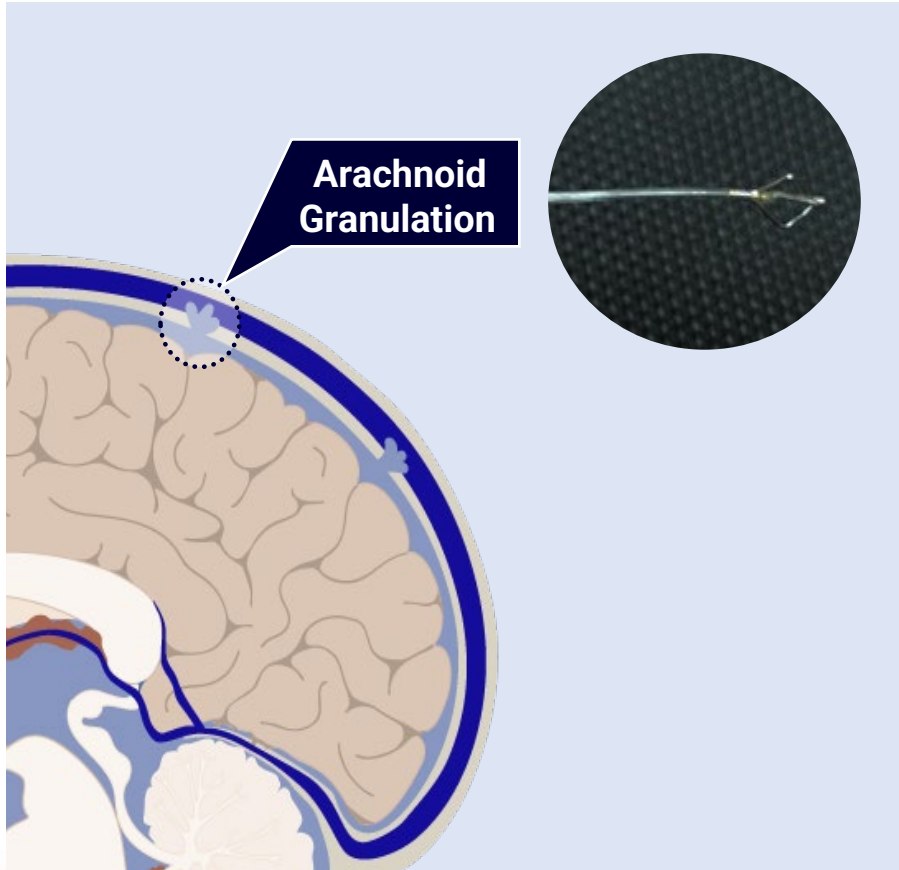
Complication Type	Incidence	Symptoms
Obstruction or occlusion	8-64%	Headache, nausea, vomiting, cognitive deficits, coma, death
Ventricular catheter misplacement	36-60%	Neurological impairment, vascular injury, intracerebral hemorrhage, death
Over-drainage	2-50%	Subdural hematoma, headache, confusion, dizziness, nausea and vomiting, lethargy, weakness, seizures, death
Infection	2-15%	Fever, altered mental state, local inflammatory signs, abdominal pain, neck stiffness, headache, vomiting, death
Mechanical failures	9-12%	Headache, nausea, vomiting, cognitive deficits, coma, death

1. Merkler AE, Ch'ang J, Parker WE, Murthy SB, Kamel H. The Rate of Complications after Ventriculoperitoneal Shunt Surgery. *World Neurosurg*. 2017;98:654-658. doi:10.1016/j.wneu.2016.10.136
2. Wallace AN, McConathy J, Menias CO, Bhalla S, Wippold FJ 2nd. Imaging evaluation of CSF shunts. *AJR Am J Roentgenol*. 2014;202(1):38-53. doi:10.2214/AJR.12.10270
3. C. Sainte-Rose, J.H. Piatt, D. Renier, A. Pierre-Kahn, J.F. Hirsch, H.J. Hoffman, R.P. Humphreys, E.B. Hendrick; Mechanical Complications in Shunts. *Pediatr Neurosurg* 1 January 1991; 17 (1): 2-9.
4. Michael J Schneck MD, Alexandria Pecoraro MD. Neurosurgical shunts and their complications. In: Lewis SL, Editor-in-Chief. *MedLink Neurology*. San Diego: MedLink, LLC. Available at www.medlink.com. Updated: January 15, 2024.
5. Kast J, Duong D, Nowzari F, Chaddock WM, Schiff SJ. Time-related patterns of ventricular shunt failure. *Childs Nerv Syst*. 1994;10(8):524-528. doi:10.1007/BF00335075
6. US Food and Drug Administration. Risks of CSF shunts. Updated August 17, 2023. Accessed June 4, 2026. <https://www.fda.gov/medical-devices/cerebral-spinal-fluid-csf-shunt-systems/risks-csf-shunts>

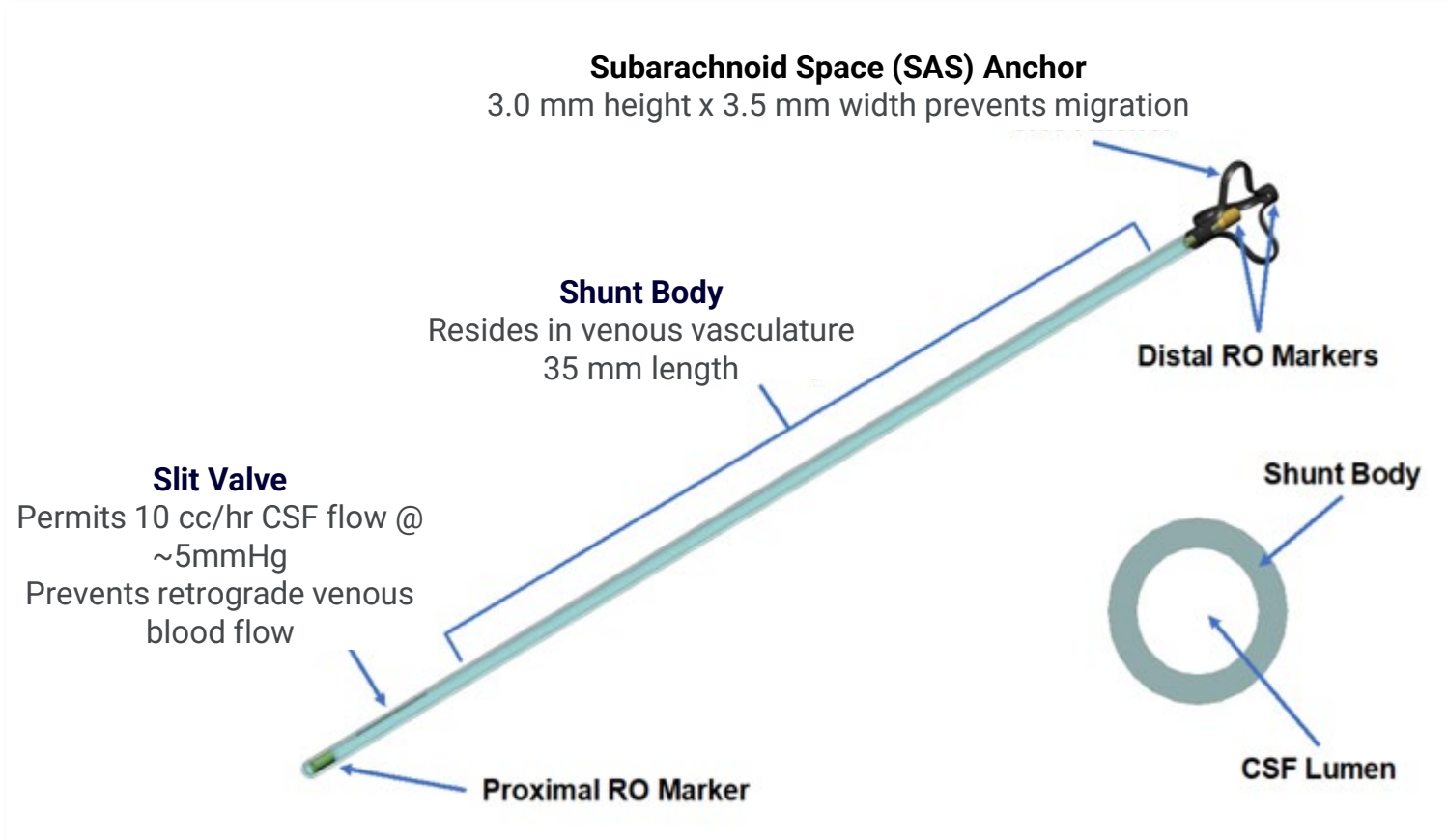
The eShunt[®] Implant is a **minimally invasive**, endovascular device designed to mimic the arachnoid granulation system of CSF absorption



Mimicry of Arachnoid Granulation System



Device Design Details

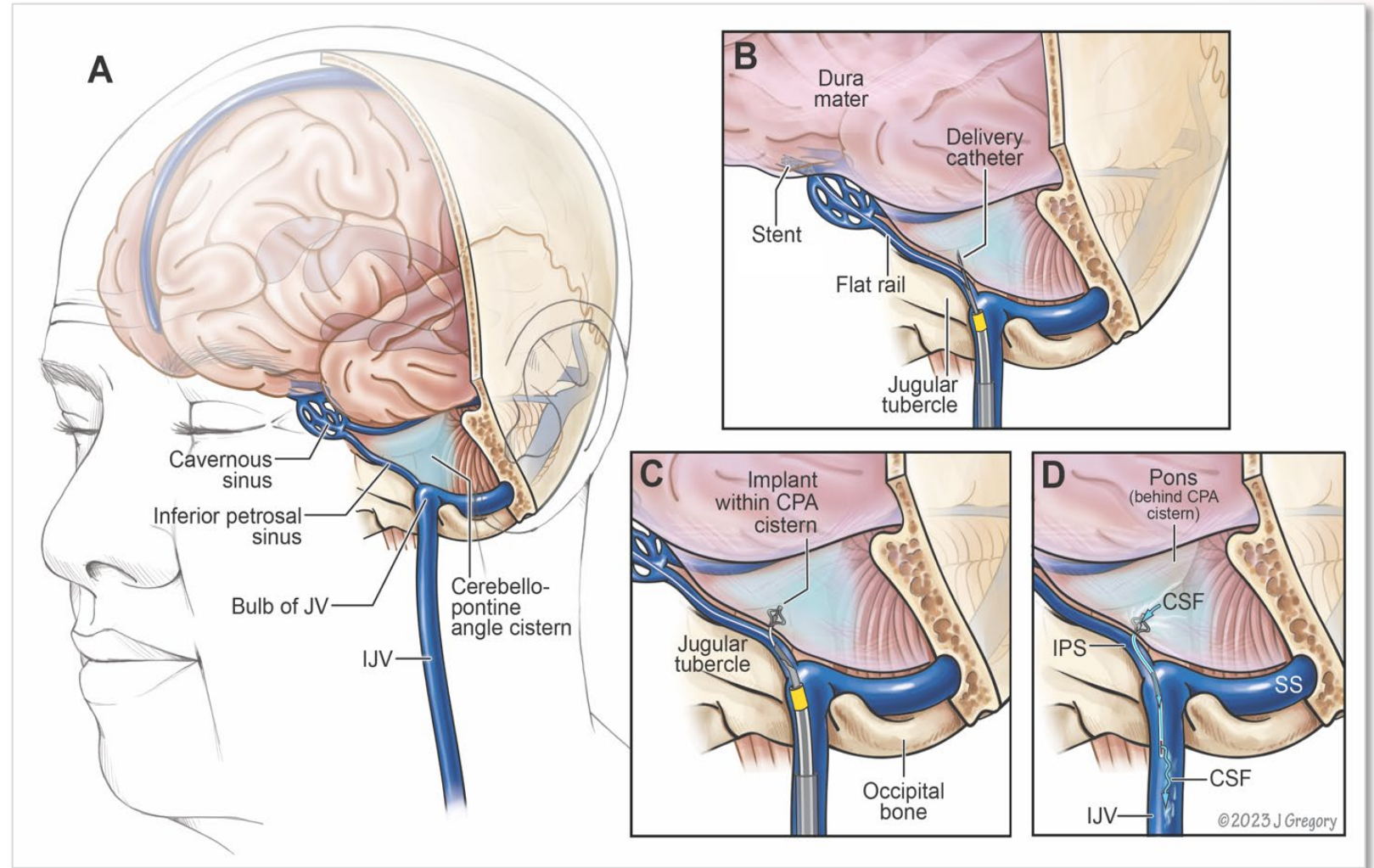


The eShunt[®] Implant is a **minimally invasive**, endovascular device designed to mimic the arachnoid granulation system of CSF absorption



Procedure Overview

1. Femoral endovenous access
2. Navigation to internal jugular vein
3. Entrance to the inferior petrosal sinus (IPS)
4. eShunt[®] Delivery Catheter navigation
5. Shunt is introduced through dura mater with shunting implant positioned in subarachnoid space
6. Catheter withdrawal and closure



NPH Single-Arm Studies Overview: demonstrate safety of eShunt[®] procedure and safety / efficacy of eShunt[®] implant in small sample



DESIGN

Prospective, non-randomized, open-label, multi-center, pilot study in subjects with normal pressure hydrocephalus for whom a traditional CSF shunt implant is indicated

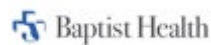
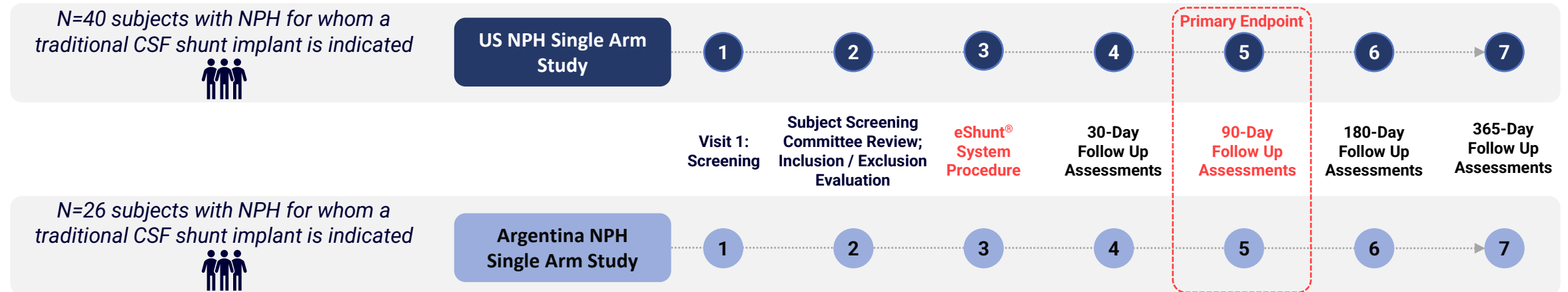
SAFETY

Rate of occurrence of device and/or procedure-related serious adverse events (SAEs) through 90 days post-procedure, as adjudicated by the Data Monitoring Committee (DMC)

EFFICACY

Improved clinical presentation **90 days** following the eShunt[®] Procedure in **any one of the three clinical presentations**, compared to baseline:

- **Gait** improvement – Timed Up and Go Test (TUG)
- **Cognitive** improvement – MoCA score increase
- Reduced **urinary** symptoms – Neurogenic Bladder Symptom Score



90 Day Single-Arm Study Results Published in JNIS



New devices and techniques



Original research

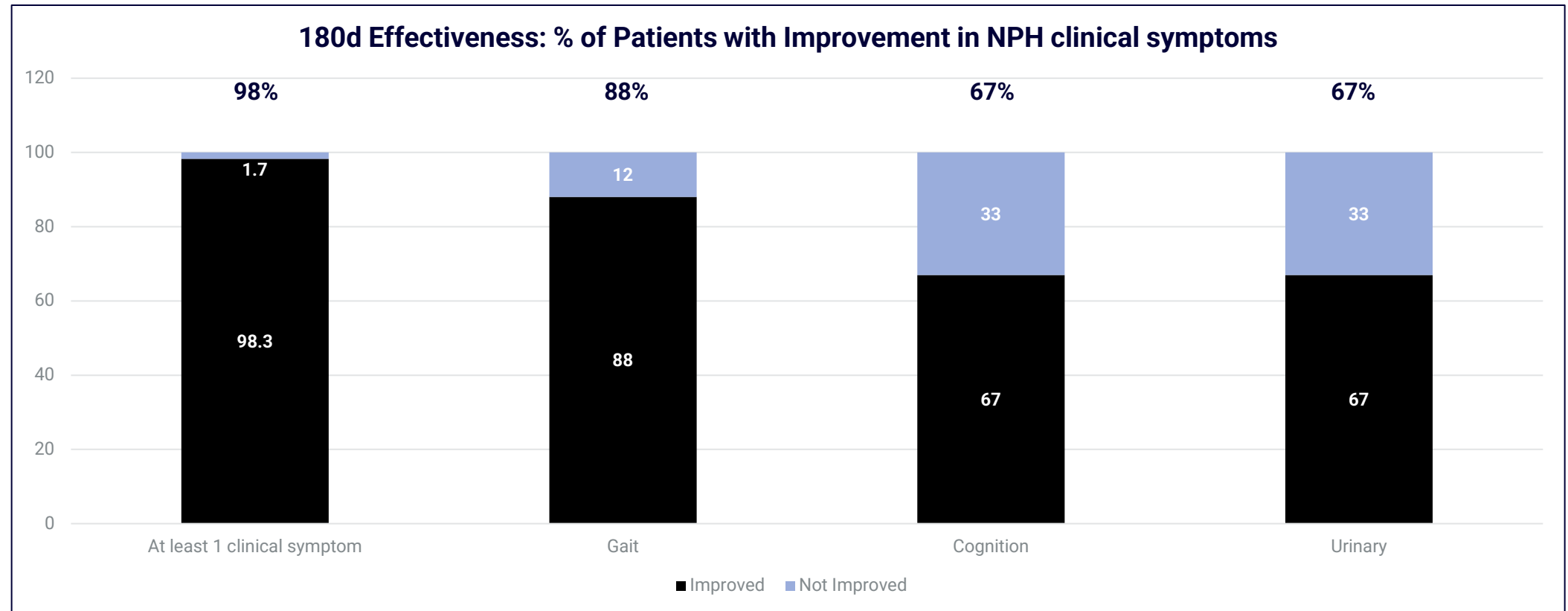
Safety of endovascular shunting for normal pressure hydrocephalus from a prospective, multicenter, single-arm study

Pedro Lylyk,¹ Charles C Matouk ,² Ricardo A Hanel ,³
John F Reavey-Cantwell ,⁴ Howard A Riina,⁵ David J Altschul ,⁶
Adnan H Siddiqui ,^{7,8} Justin F Fraser ,⁹ Koji C Ebersole,¹⁰ Tarun Bhalla,¹¹
Matthew T Bender ,¹¹ Christopher S Ogilvy ,¹² Philipp Taussky,¹²
Amanda Baker,¹³ Mahesh V Jayaraman ,¹⁴ Ivan Lylyk ,¹⁵ Nicolas Perez ,¹⁶
Carlos Bleise ,¹ Esteban Scrivano,^{1,17} Pedro N Lylyk,¹⁷ Kamil W Nowicki,¹⁸
Andrew B Koo ,¹⁹ Joseph Antonios ,² Brandon M Beneduce,²⁰ Elad I Levy ,^{7,8}
Carl B Heilman,²¹ Adel M Malek ²¹

Sustained Effectiveness at 180-days



98% of patients demonstrated improvement in at least one of the three predominant clinical symptoms of gait, cognition and urinary symptoms. 88% demonstrated improvement in gait, the primary effectiveness endpoint in STRIDE, compared to 75% literature reported¹ improvement for VP shunt patients



Sustained Safety at 180 Days: No Further SAE's

Incidence of Treatment-Emergent Related Serious Adverse Events After Procedure



Adverse Event MedDRA Coding	Total Subjects (N=66)			
Preferred Term	Device or Procedure Related	Device Related	Procedure Related	Device & Procedure Related
TOTAL N (%) events [CI for %]	2 (3.0%) 2 [0.4%, 10.5%]	0 (0.0%) 0 [0%, 5.4%]	2 (3.0%) 2 [0.4%, 10.5%]	0 (0.0%) 0 [0%, 5.4%]
Femoral artery pseudoaneurysm N (%) events	1 (1.5%) 1	0 (0.0%) 0	1 (1.5%) 1	0 (0.0%) 0
Cerebral venous sinus thrombosis N (%) events	1 (1.5%) 1	0 (0.0%) 0	1 (1.5%) 1	0 (0.0%) 0

A treatment-emergent AE is any AE that begins or increases in severity after the initiation of the eShunt® procedure.

n = number of subjects who experienced the event at least once. % = n/N. e = number of events.

CI = 95% exact Clopper-Pearson confidence interval for the percentage.

Seriousness, device relatedness, and procedure relatedness as determined by the adjudication committee.

Relatedness of each AE is classified as unrelated, possibly, probably or definitely. Relatedness of probably and definitely are considered as related in this table.

Preferred terms are coded using the MedDRA dictionary.

Subjects are counted once in the numerator for each row in which they had at least one event, therefore, subject counts for sub-categories may not add up to the main category subject count.

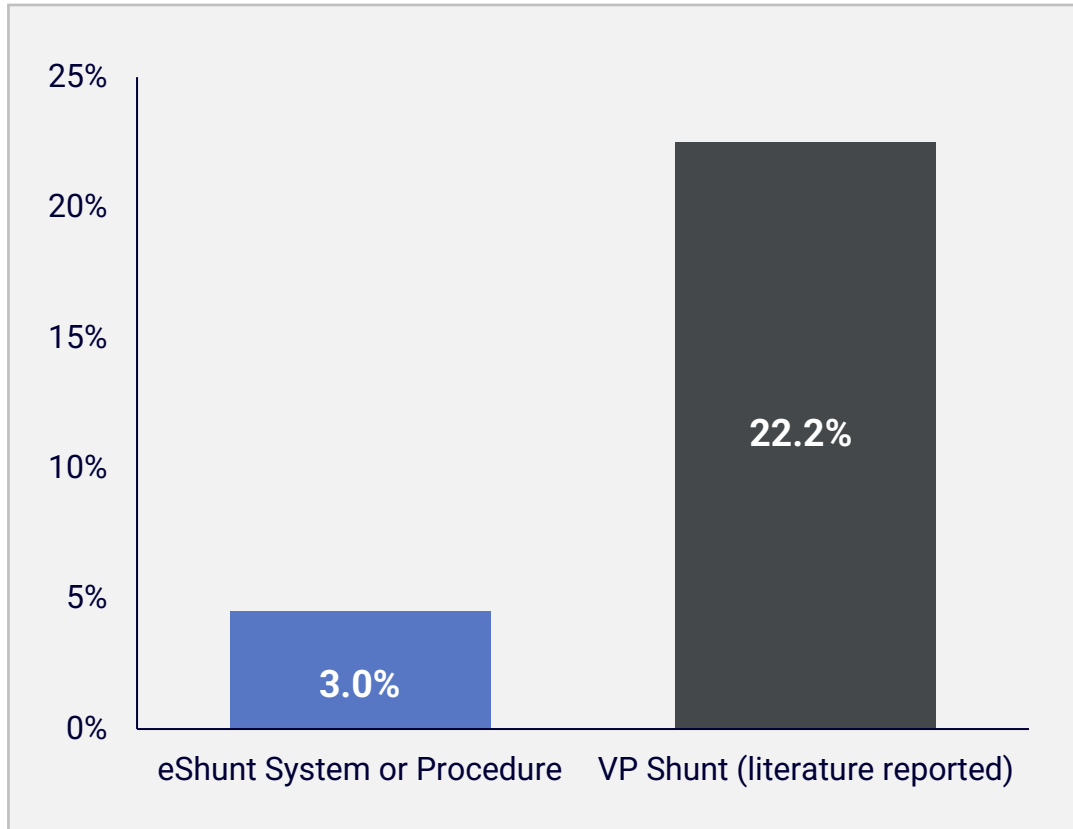
Summary / Context:

- **3%** procedure-related SAE rate
- **0%** eShunt® device-related SAE rate
- Rates are competitive with any neurointerventional implant
- VP shunt SAE rates reported in literature ~22%+

eShunt® System demonstrates favorable safety profile at 180 days compared to standard of care



3.0% rate of Serious Adverse Events (related to eShunt® procedure¹), compared to 22.2% as reported in PENS (90d)



Review of patients imaging (MRI and/or CT) was completed by an independent neuroradiology core lab



No radiographic evidence of over drainage

- Compared to 10.3% reported in literature for VP shunts³

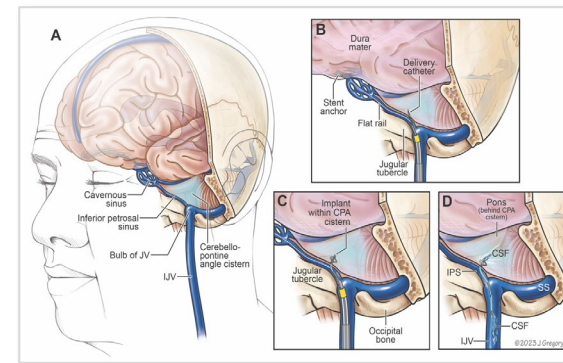
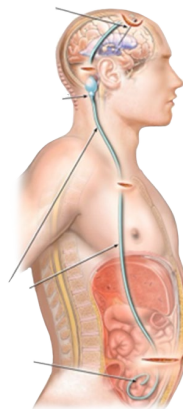


No radiographic evidence of cerebral or intracranial hemorrhage

- Compared to 4.4% reported in literature for VP shunts³

1) eShunt® rate: CereVasc, data on file
2) VP shunt rate: NPH literature performance goal; as submitted to FDA in G220002/S008
3) Internal document: NPH complication comparison_202502

Current Procedure (VP Shunt) Compared to eShunt System



	VP Shunt	eShunt System
Procedure Type	Open	Percutaneous (Endovascular)
Source of CSF	Cerebral Ventricles	Subarachnoid Space (CPA Cistern)
CSF Drainage Location	Peritoneum	Venous System (IPS/Jugular Vein)
ICD-10-PCS	<i>Bypass Cerebral Ventricle to Peritoneal Cavity with Synthetic Substitute, Open Approach</i>	<i>New code requested</i>



Procedural Documentation

Use of the eShunt[®] System will be documented by a neurointerventional surgeon or an endovascular neurosurgeon in the following segments of the medical record.

- Interventional radiology procedure log (with device implant record)
- Operative report
- Postoperative procedural notes in progress notes
- Discharge summary

Terminology describing the CereVasc eShunt[®] System will be included in the procedure report and may be referred to as:

- CereVasc eShunt[®] Implant
- CereVasc eShunt[®] System
- CereVasc eShunt[®]
- eShunt[®] Implant
- eShunt[®] System
- eShunt[®]

Regulatory Information



- The CereVasc eShunt® System received FDA Breakthrough Device designation for adult normal-pressure hydrocephalus in August 2024, as well as for pediatric hydrocephalus in April 2025.
- CereVasc anticipates FDA Premarket Authorization (PMA) approval for the eShunt® System in 2028.