# Intracranial Aneurysms: Trials for Intrasaccular Devices in the United States

An update on the United States clinical trial landscape and evolving evidentiary standards for intrasaccular flow disruption.

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Wide neck bifurcation aneurysms remain among the most technically challenging lesions in endovascular practice. Conventional coil embolization is limited by instability and recurrence in unfavorable dome-to-neck ratios. Adjunctive techniques such as balloon remodeling and stent-assisted coiling expand options but increase complexity and require dual antiplatelet therapy (DAPT), which is problematic in ruptured aneurysms and patients at high bleeding risk.

Flow diversion transformed the management of sidewall aneurysms by promoting endothelialization across the aneurysm neck. However, at bifurcation sites, branch incorporation and continued antiplatelet requirements can limit its applicability.[1,2] These limitations created the need for a strategy that promotes aneurysm thrombosis while preserving the parent circulation without long-term antiplatelet therapy.

Intrasaccular flow disruptors were introduced to address this gap. The Woven EndoBridge (WEB) device (Terumo Neuro) entered European practice in the early 2010s and was subsequently evaluated in the United States through the WEB-IT trial, leading to FDA approval in 2018.[3,4] Early clinical experience demonstrated favorable safety and reproducibility across multiple centers, with high rates of adequate occlusion in wide neck bifurcation aneurysms. Longer-term follow-up clarified its durability and highlighted an important distinction between adequate occlusion and complete aneurysm cure.[5]

Intrasaccular flow disruptors were introduced almost entirely through prospective investigational device exemption (IDE) trials incorporating standardized composite endpoints, independent core laboratory imaging review, and adjudicated safety outcomes. This article focuses on the United States clinical trial landscape and evolving evidentiary standards for intrasaccular flow disruption.

## WEB DEVICE

The clinical foundation for intrasaccular therapy in the United States was established by the WEB-IT trial, a prospective, multicenter IDE study that enrolled 150 patients across 27 centers with wide neck bifurcation aneurysms located at the middle cerebral artery (MCA) bifurcation, basilar apex, anterior communicating artery, and internal carotid artery terminus.[3,4] WEB-IT evaluated performance across diverse practice settings.

At 12 months, adequate occlusion was achieved in approximately 85% of treated aneurysms, with complete occlusion observed in 50% to 55%.[3] Major morbidity and mortality were low, confirming safety. These findings were pivotal in securing FDA approval and establishing the device as a viable alternative to reconstructive strategies in appropriately selected lesions.

Long-term follow-up further clarified the durability profile of the technology. At 5 years, stable or improved occlusion was observed in approximately 87% of cases, with retreatment required in about 11%, most occurring within the first year.[5] No delayed aneurysm ruptures were reported.

Compared with clipping (> 90%) and stent-assisted coiling (65%-80%), intrasaccular therapy improves safety and avoids long-term antiplatelet therapy but has lower complete occlusion rates.[6-8] The CLARYS study confirmed safety without DAPT in ruptured aneurysms with a 0% incidence of rebleed events.[9] The CLEVER study demonstrated continued improvements in outcomes and similar occlusion rates with the WEB 17 system.[10]

**TABLE 1. CURRENT AND EMERGING UNITED STATES CLINICAL TRIALS AND INVESTIGATIONAL DEVICES FOR INTRASACCULAR ANEURYSM TREATMENT**

| Trial | Device (Manufacturer) | Design | Population |
|---|---|---|---|
| WEB-IT (NCT02191618)[11] | Woven EndoBridge (WEB) (Terumo Neuro) | Pivotal, prospective, single-arm IDE | WNBA |
| WEB-IT (5-y)[5] | WEB (Terumo Neuro) | IDE cohort long-term follow-up | Same cohort |
| CERUS (NCT03680742)[12] | Contour neurovascular system (Stryker) | Prospective, multicenter, single arm | Nonruptured bifurcation aneurysms |
| US Contour IDE (NCT04852783)[13] | Contour/Contour 021 neurovascular system (Stryker) | Prospective, multicenter, single-arm IDE (PMA-supporting) | Wide neck bifurcated saccular IAs (ruptured/unruptured; H&H I–III for ruptured) |
| Contour NEXT (NCT06693011)[14] | Contour neurovascular system (Stryker) | Continued access IDE | Wide neck saccular IAs (bifurcation; ruptured/unruptured) |
| Pre-SEAL IT (NCT05686733)[15] | SEAL saccular endovascular aneurysm lattice system (Galaxy Therapeutics, Inc.) | First-in-human, prospective, single arm | Ruptured/unruptured saccular IAs |
| SEAL-IT (NCT05831202)[16] | SEAL (Galaxy Therapeutics, Inc.) | Prospective, multicenter, single-arm IDE (PMA supporting) | WNBA, sidewall, and ruptured cohorts |
| ARTISSE IDE (NCT02998229)[17] | Artisse intrasaccular device (Medtronic) | Prospective, multicenter, single-arm IDE | WNBA (ruptured/unruptured; H&H grade I-II for acute rupture) |
| INSPIRE-A (Artisse cohort, Europe)[18] | Artisse 2.0 (Medtronic) | Prospective registry (real world) | Wide neck aneurysms (ruptured + unruptured) |
| HARBOR pilot (NCT07117526)[19] | Harbor occlusion device (Nuvascular Inc.) | Prospective, single-center, single-arm pilot | Unruptured saccular IAs (2.5-12 mm) |
| TORNADO (NCT05550571)[20] | Nautilus intrasaccular system (EndoStream) | Prospective, multicenter, single-arm IDE | Acutely ruptured wide neck saccular aneurysms (neck 4-7 mm; dome ≥ 5 mm; H&H grade I-III) |
| CITADEL embolization device study (NCT04057352)[21] | Citadel embolization device + target detachable coils (Stryker) | Prospective, multicenter, single arm, nonrandomized | Unruptured/ruptured wide neck saccular IAs (6-12 mm; bifurcation or sidewall) |

Abbreviations: DSA, digital subtraction angiography; H&H, Hunt and Hess; IA, intracranial aneurysm; IDE, investigational device exemption; ITT, intention to treat; LOCF, wide neck bifurcation aneurysm.

However, complete occlusion rates remain suboptimal. There is still some debate as to what constitutes an adequate occlusion, and the significance of residual neck filling remains unclear. As a result, durability and the need for retreatment are key considerations for future research.

## EMERGING AND ONGOING UNITED STATES TRIALS

Several next-generation platforms are being evaluated in the United States, focusing on improving neck coverage and durable occlusion (Table 1).[5,11-21] Representative

| | Sample Size | Follow-Up Duration/ Schedule | Key Outcome | Status |
|---|---|---|---|---|
| | 150 enrolled; 148 treated; 143 with 12-mo angio | Index + 6 mo, 12 mo core lab imaging | Primary safety event, 0.7% (1/148); 12-mo complete occlusion, 53.8% (77/143); adequate occlusion, 84.6% (121/143) | Completed; FDA approved |
| | 150 enrolled; 83 with 5-y imaging; 123 clinical follow-up | Core lab imaging at 6 mo and 1, 3, and 5 y | No rebleeding (0/9 ruptured; 0/141 unruptured); 5-y complete occlusion 58.1%, adequate 87.2% (LOCF); 18 retreatments after 1 y | Completed |
| | 34 enrolled; 32 implanted | 6 mo (primary); 12 mo secondary | Complete occlusion 44% at 6 mo and 69% at 12 mo (PP); adequate occlusion 84% at last available follow-up; primary safety endpoint met in 2 ITT patients | Completed (EU premarket/CE Mark supportive) |
| | Up to 220 planned (CenterWatch notes 250) | Not specified (trial runs through 2030) | Outcomes pending (study designed to collect safety + effectiveness for FDA submission) | Active, not recruiting |
| | 250 | Follow-up at 1, 12, and 24 mo | Outcomes pending (continued access data collection) | Active, recruiting |
| | 26 | 24h, 3 mo (MRA), 6, 12, 24 mo | 29 patients/33 aneurysms; 100% technical success; 3-mo complete occlusion, 74.1% (20/27); adequate occlusion, 81.5% (22/27); no periprocedural stroke or new SAH to 3 mo | Completed (trial listing) |
| | 279 | 24 h/discharge, 3, 6, and 12 mo (DSA required), then annual to 5 y | Interim: 223 enrolled; technical success: 100% WNBA/97.1% sidewall/100% ruptured; early complete occlusion: 95.7% (22/23) at 3 mo and 100% (3/3) at 6 mo; no periprocedural permanent strokes/new SAH after 3 mo | Enrollment complete reported publicly |
| | 220 | Primary effectiveness assessed at 1 y | Outcomes pending (IDE trial ongoing) | Active, recruiting |
| | 87 | 6-mo follow-up (interim analysis) | Implantation success, 96.6% (84/87); device-related SAE, 1.3%; overall stroke, 2.3%; 6-mo complete obliteration, 80.0% (28/35) in unruptured with no recurrences/retreatments | Ongoing registry; interim data reported |
| | 10 (estimate enrollment) | Primary endpoint time frame, 10-14 mo (~1 y) | Primary effectiveness: complete occlusion at ~1 y without retreatment/recurrent SAH and without parent artery stenosis > 50% | Recruiting |
| | 45 | Follow-up through 1 y | Safety and probable benefit (outcomes pending) | Active, not recruiting |
| | 150 (expected) | Total participation up to 15 mo (follow-up visits + phone check-ins) | Outcomes pending (safety and effectiveness) | Active, not recruiting |

last observation carried forward; PMA, premarket approval; PP, per protocol; SAE, serious adverse event; SAH, subarachnoid hemorrhage; US, United States; WNBA,

angiographic outcomes across multiple intrasaccular platforms are shown in Figures 1 to 4.

The SEAL saccular endovascular aneurysm lattice system (Galaxy Therapeutics, Inc.) is a next-generation platform being evaluated in the SEAL-IT pivotal trial (NCT05831202).[16] Preliminary data from the first 254 treated patients demonstrated a 100% technical success rate and an 84.5% complete occlusion rate on early imaging, suggesting the potential for improved complete occlusion compared with earlier-generation devices.[16,22]

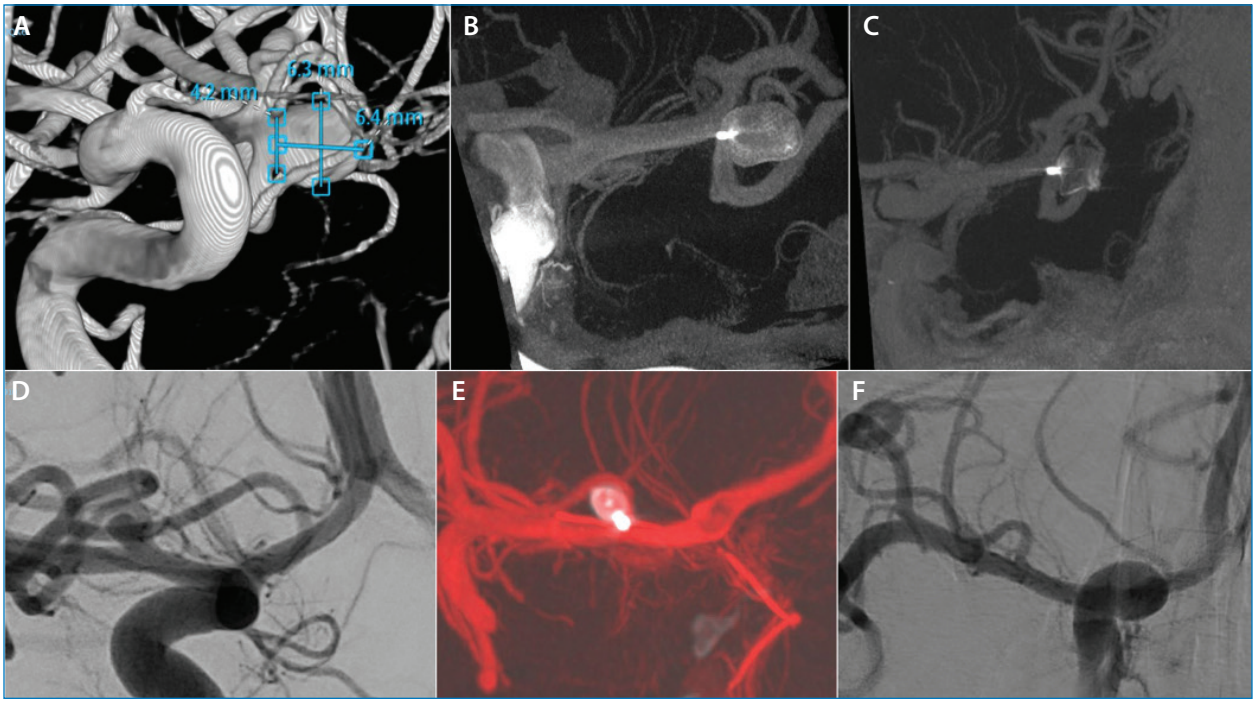


**Figure 1. Representative Galaxy device cases. Left MCA aneurysm treated with a 9- X 3-mm Galaxy device showing pretreatment angiographic anatomy, immediate postdeployment, and 12-month follow-up with stable occlusion (A-C). Right MCA aneurysm treated with a 4- X 4-mm Arc Galaxy device demonstrating durable occlusion at 12 months (D-F).**

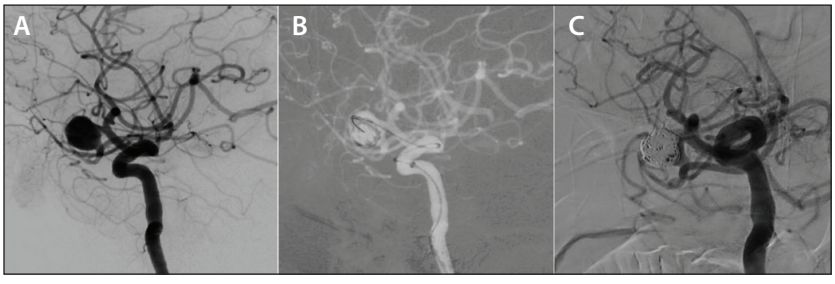


**Figure 2. Right MCA aneurysm treated with the Trenza device (Stryker). Pretreatment angiography (A), immediate postdeployment angiography (B), and 12-month follow-up demonstrating maintained aneurysm occlusion (C).**

The Artisse intrasaccular device (Medtronic) represents another evolution in design.[17] This flared nickel-titanium intrasaccular flow disruptor is engineered to improve circumferential wall contact in wide neck bifurcation aneurysms and is delivered through a 0.021-inch microcatheter. The ongoing United States ARTISSE IDE study (NCT02998229) is actively recruiting and is expected to complete primary data collection by 2027. European registry experience from the INSPIRE-A study (NCT02988128) demonstrated a 96.6% implantation success rate and 80% complete obliteration of unruptured aneurysms at 6 months,[18] supporting continued evaluation in a regulated United States trial setting.

The Harbor occlusion device (Nuvascular Inc.) is being evaluated in a United States pilot IDE study (NCT07117526), assessing 1-year occlusion without retreatment or parent artery narrowing in patients with a single, unruptured intracranial aneurysm.[19]

The Contour neurovascular system (Stryker) has shown feasibility and adequate occlusion in European studies, and a United States IDE has completed enrollment and is awaiting primary outcome results.[12,23-25] The Neqstent coil-assisted flow diverter (Stryker), which acts as a neck bridging device, is not available in the United States but is used regularly in Europe. The Nautilus intrasaccular system (EndoStream) uses a similar approach to the Neqstent, with early feasibility data completed in the United States.[26] Currently, this system is being submitted for humanitarian device exemption approval to the FDA. The Citadel embolization device (Stryker) offers a different endosaccular approach, using a braided coil matrix to act as a neck bridge.[21] The IDE trial has completed enrollment, and we are awaiting primary outcome data.

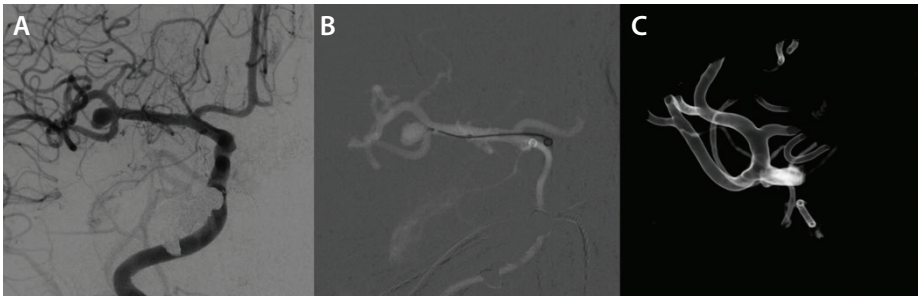


**Figure 3. Right MCA aneurysm treated with the Contour device (5 mm). Pretreatment angiography (A), immediate postdeployment angiography (B), and 12-month follow-up demonstrating adequate aneurysm occlusion (C).**

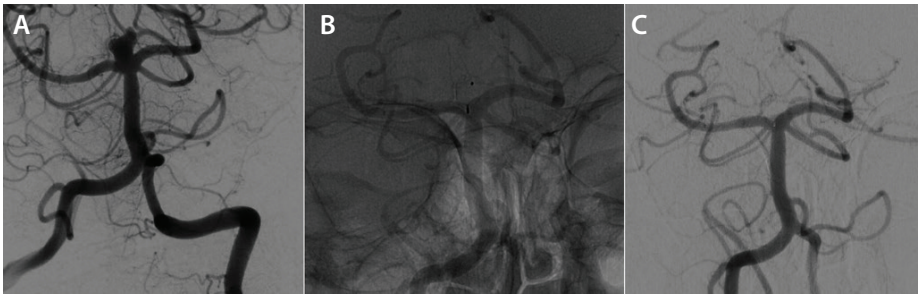


**Figure 4. Basilar apex aneurysm treated with the WEB device (7 X 3 mm SL). Pretreatment angiography (A), immediate postdeployment angiography (B), and 12-month follow-up demonstrating stable aneurysm occlusion (C).**

No randomized comparisons with established treatments exist, and future work should focus on durability and comparative effectiveness.

## LIMITATIONS AND FUTURE DIRECTIONS

Despite encouraging safety and midterm durability data, several limitations continue to define the current evidence base for intrasaccular therapy. Most notably, no randomized controlled trials have directly compared intrasaccular flow disruption with competing reconstructive endovascular strategies or microsurgical clipping. Existing comparisons rely on observational data and are subject to selection bias and confounding variables.[2,27]

Reliance on composite endpoints such as 12-month adequate occlusion may not reflect true cure, and variability in grading and follow-up complicates comparisons.[28] Moreover, durability data beyond 5 years remain limited and are influenced by loss to follow-up and heterogeneous imaging surveillance strategies.[5,24] Modest IDE cohort sizes limit evaluation across diverse aneurysm types. Of particular interest is the role of intrasaccular technology for sidewall aneurysms, but data are limited. The SEAL-IT trial evaluating the SEAL system does have a sidewall aneurysm arm, and prospective data should be forthcoming.

Additional gaps include lack of standardized retreatment criteria, limited cost data, and minimal patient-reported outcomes. These omissions are increasingly relevant in the management of unruptured aneurysms, where decision-making is often preference-sensitive and influenced by perceived invasiveness, durability, surveillance burden, and anxiety related to residual filling.[29,30]

Future progress in intrasaccular therapy depends on moving beyond feasibility and regulatory milestones toward long-term durability and comparative effectiveness. Pragmatic randomized trials, registry-embedded studies, and adaptive trial designs offer potential pathways for evaluating new devices in real-world populations while maintaining methodologic rigor and generalizability.[31,32] Greater standardization of occlusion grading, imaging protocols, and retreatment thresholds would further enhance interpretability across studies. Finally, incorporation of patient-centered outcomes, including quality of life and treatment burden, should complement angiographic endpoints to better reflect the realities of contemporary aneurysm care.

## CONCLUSION

In the United States, trials of intrasaccular flow disruption have moved beyond feasibility to focus on achieving durable complete occlusion while maintaining safety. The WEB-IT study is a key example, showing low early complications and strong occlusion rates at 12 months, with good results over longer follow-up. As new devices and designs are developed, upcoming results will focus on durability, retreatment rates, and consistent long-term follow-up. In the end, the role of next-generation intrasaccular devices will depend on their durability beyond 1 year, consistent retreatment criteria, and how they compare to reconstructive endovascular and microsurgical treatments, along with better identification of which aneurysm types and patient groups will benefit most. ■

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