



August 2026 | Issue 1

Congenital Cardiovascular Interventional Study Consortium (CCISC)

www.ccisc.net

Occlutech ASD Module Newsletter

CRISP Registry | Real-World Use Surveillance of the Occlutech ASD Occluder

CASES ENROLLED

152

at 12 U.S. centers

OF 500-CASE GOAL

30%

7-year follow-up

ENROLLED IN 2026

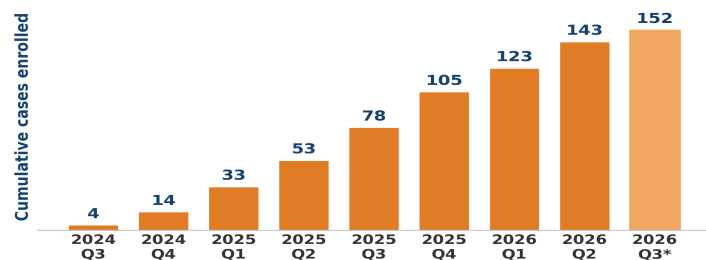
47

year to date

ENROLLMENT UPDATE

152 cases at 12 U.S. centers toward a goal of 500 cases at 20–25 centers, with follow-up through 7 years post-implant — our first newsletter dedicated to the module.

Cumulative enrollment is accelerating



2026 Q3 in progress. 47 cases enrolled year to date in 2026.

NEW: real-time follow-up tally

Follow-up	Eligible	Complete	Pending	%
Discharge	147	138	9	93.9%
1 month	137	118	17	86.1%
6 months	103	83	19	80.6%
12 months	49	31	18	63.3%

Any visit from 9 to 24 months post-implant counts toward the 12-month data point.

PLEASE ENTER YOUR 12-MONTH FOLLOW-UP DATA

- **The 12-month visit is our primary outcome measure timepoint.** Both primary endpoints — SAE and closure success — are assessed at approximately 12 months after implant.
- **The visit does not have to fall exactly at 12 months.** As an observational surveillance study, we accept any routine clinical follow-up from 9 to 24 months post-implant — including visits already documented in your charts.
- The tally updates in real time as data are entered — the more we capture, the stronger the evidence.

ENROLLMENT BY SITE

Site	Cases	Site	Cases
Nicklaus Children's	28	Children's Hospital New Orleans	9
St. Louis Children's	27	University of Virginia	9
Joe DiMaggio Children's	22	Ann & Robert H. Lurie Children's	4
Children's Hospital Colorado	19	Duke Health	3
University of Minnesota	19	Inova Health Care	2
Arnold Palmer Hospital	9	Johns Hopkins All Children's	1

Thank you to Nicklaus, St. Louis, and Joe DiMaggio Children's for outstanding enrollment and data entry.

PICS 2026 — SAN DIEGO, CA | AUGUST 30 – SEPTEMBER 2

- **Our abstract was accepted as an oral presentation.** "Early U.S. Real-World Experience with the Occlutech ASD Occluder," presented by Daisuke Kobayashi. 121 patients, 96% technical success, 93% procedure success, 1.7% safety events, and successful closure in 21 of 22 patients <10 kg.
- **CCISC Meeting — Tuesday, September 1, 12:45–1:45 pm, Marriott Ballrooms 1 & 2.** Daniel Duarte (Nicklaus Children's) will present the module progress update.

Interested in joining? Any CRISP Registry site implanting the Occlutech ASD Occluder is eligible. Contact **Daisuke Kobayashi** (daisuke@wustl.edu) or **Nancy Sullivan** (Nsullivan@mhs.net).

Data as of August 2026. Sponsoring organization: CCISC. Module supported by Occlutech.