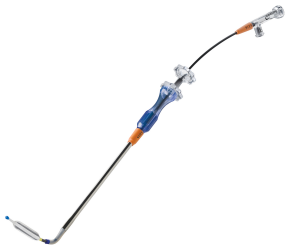
Integra LifeSciences Announces 100th Patient Enrolled in AERA® Pediatric Registry

Sep 29, 2026

Prospective, multicenter registry advances toward planned enrollment of 300 pediatric patients

PRINCETON, N.J., Sept. 29, 2026 (GLOBE NEWSWIRE) -- Integra LifeSciences (Nasdaq: IART), a leading global medical technology company, announced today the enrollment of the 100th patient in the AERA® Pediatric Registry, a prospective, multicenter observational registry evaluating the real-world clinical performance of the Acclarent AERA Eustachian Tube Balloon Dilation System in pediatric patients eight or older.

ACCLARENT AERA® Eustachian Tube Balloon Dilation System



ACCLARENT AERA® Eustachian Tube Balloon Dilation System

The milestone represents one-third of the registry's planned enrollment of 300 patients and reflects the continued collaboration of participating investigators, research coordinators and clinical sites across the United States. Launched in July 2025, the registry is designed to generate real-world evidence regarding the use of AERA in children with obstructive Eustachian tube dysfunction, or ETD.

"Reaching the 100-patient milestone reflects meaningful progress in building real-world evidence in pediatric Eustachian tube dysfunction and its treatment," said Christopher Schutt, M.D., vice president, Operations & Excellence, Office of the Chief Medical Officer, Integra LifeSciences. "We are grateful to the research teams and families whose participation is making this work possible. We are hopeful their contributions will help inform future clinical decision-making and advance understanding of care for children with ETD."

ETD occurs when the Eustachian tube does not properly regulate pressure or drain fluid from the middle ear. The condition may contribute to symptoms including ear pressure or fullness, discomfort, hearing difficulties, and recurrent ear infections. Eustachian tube balloon dilation is a treatment option for appropriate patients with ETD.

"This milestone reinforces our commitment to the ear, nose, and throat ("ENT") market and to advancing the evidence base supporting innovative treatment options for patients with Eustachian tube dysfunction," said Harvinder Singh, executive vice president and president, Specialty Surgery, Integra LifeSciences. "We believe continued investment in clinical evidence generation is essential to supporting physicians, informing care decisions and strengthening our leadership position in ENT."

AERA received FDA clearance for its pediatric indication in December 2023, becoming the first and only Eustachian Tube Balloon Dilation System indicated for pediatric patients ages eight and older.[1]

About Integra LifeSciences

Integra LifeSciences (Nasdaq: IART) is a global medical technology leader dedicated to restoring lives. We are advancing transformational care through impactful innovation in neurosurgery and tissue reconstruction, specialized fields that demand exceptional expertise and precision. Our portfolio of highly differentiated, gold-standard technologies is trusted by healthcare professionals to deliver transformative care. For the latest news and information about Integra LifeSciences and its products, please visit www.integralife.com.

About ACCLARENT AERA® Eustachian Tube Balloon Dilation System

The ACCLARENT AERA Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older. For patients ages 8-17 years, the ACCLARENT AERA Eustachian Tube Balloon Dilation System, alone or in combination with adjunctive procedures, is intended to treat patients with objective signs of persistent obstructive Eustachian tube dysfunction from inflammatory pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive Eustachian tube dysfunction.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections and involve inherent risks, assumptions and uncertainties that are difficult to predict and which may be beyond our control. Forward-looking statements that may be discussed include, but are not limited to, the potential clinical application and efficacy of the AERA Eustachian Tube Balloon Dilation System in pediatric patients, the number of patients expected to be involved in the AERA Pediatric Registry and the anticipated utility of data collected from the AERA Pediatric Registry. There can be no assurance that the AERA Pediatric Registry will be able to meet the enrollment and observation objectives described herein or that any potential clinical applications and benefits will be observed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Integra LifeSciences's business, particularly those identified under the headings "Risk Factors" and "Special Note Regarding Forward-Looking Statements," included in Integra LifeScience's Annual Report on Form 10-K for the year ended December 31, 2025, and information contained in subsequent filings with the Securities and Exchange Commission. The forward-looking statements included in this news release are made only as of the date of this news release and Integra LifeSciences undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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[1] U.S. Food and Drug Administration. ACCLARENT AERA Eustachian Tube Dilation System (K230742). Dec. 13, 2023. Website: FDA 510(k) Clearance Database - ACCLARENT AERA K230742 [accessdata.fda.gov]

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/4ef670f8-0782-4879-8f56-55f9ef15506a