

# Medical Devices Fall Short For Children

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Only 15 months old, Vivian Andorf underwent her sixth cardiac catheterization. Her cardiologist inserted a flexible tube through a tiny artery in her leg and wended it to her heart in an attempt to treat her narrowed veins and arteries, the result of a congenital condition.

In prior procedures, the first of which she had at a mere 3 weeks old, an adult-size catheter had to be used. Catheters sized for a child, let alone an infant, were not available. The larger catheter took longer to insert and was more likely to injure her already abnormal blood vessels, said her cardiologist, Dr. Alex Golden of the Cleveland Clinic Children's Hospital.

"It's trying to put something too large into something smaller," he said.

But during the sixth procedure, Vivian became just the second young patient in the country to benefit from a catheter approved by the Food and Drug Administration for use in children. It is a rare success in the field of pediatric medical devices.

The development of surgical tools and medical devices designed for children lags a decade behind device development for adults. The lag, say experts, can be blamed largely on economics. The pediatric market is far smaller than the market for adults, making it difficult for companies to recoup research and development expenses for smaller devices.

"Innovation in medicine is driven by need, but also by the market," said Dr. Michael R. Harrison, the director emeritus of the Fetal Treatment Center and the director of the Pediatric Device Consortium, both at the University of California, San Francisco. "Big markets have lots of folks developing devices, but small markets like the pediatrics market don't."

Take, for example, the field of knee and hip replacements in adults. "There's been an incredible amount of investment and talent and innovation devoted to those things," said Dr. Harrison, "but essentially none to pediatric orthopedic devices."

So for decades, pediatric surgeons and other specialists have had to make do, using adult-size devices "off label" in children. They might chisel out their own smaller surgical tools in workshops, or jury-rig devices to squeeze into their tiny patients. Always, they contend with the extra challenges that come with using a device that's not quite right.

"Often we end up having to dramatically modify an operation simply to be able to implant a device in a child," said Dr. Pedro del Nido, chairman of the department of cardiac surgery at Boston Children's Hospital.

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Among the adult devices used with children are stents, defibrillators, pacemakers, artificial mitral valves, chemotherapy delivery devices, kidney dialysis systems, and metal implants that help straighten a spine or replace a piece of bone.

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