

“In-Body” Pediatric Devices Pose Unique Challenges

Implantable medical devices help improve the health of millions of people. Usually placed in patients’ bodies through surgery, these devices treat a wide range of medical conditions, including cardiac and nervous system disorders.

The Food and Drug Administration (FDA) regulates all medical devices through its Center for Devices and Radiological Health (CDRH).

Many of the implantable devices FDA regulates have been approved for pediatric use, meaning they can be used by people who are under the age of 21. Some of these devices are designed specifically for children and adolescents, while others are adapted from adult uses.

Devices for these younger groups present unique challenges, particularly for scientists who design the devices, health care professionals who recommend them, and parents and guardians who directly oversee their use.

Factors to Consider

Several factors may be considered in regard to implantable devices for children and adolescents. These include



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When it comes to implantable devices for children and adolescents, factors to consider include how active the child is, where the child is developmentally, the child’s immunization history, and the impact the device will have on behavioral and social growth.

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Physical growth: Children and their organs will likely undergo many periods of growth.

The child's development and the condition being treated: This may call for examination of how a device may affect the patient's brain development when devices are implanted in or near the brain. It also may call for examination of potential alternate implantation sites. For example, procedures involving the chest may affect the growth of breast buds in adolescent girls.

Surgical risks specific to children: Timing of surgery in relation to patient growth, disease progression, and medical history (such as immune system competency and susceptibility to infections) needs to be addressed.

The child's ability to manage the device safely: A child's age, maturity, strength, dexterity, and motor and sensory skills should be considered.

Safety Always a Top Priority

Proper device design and labeling are important, as well as appropriate training for patients and parents. These factors can reduce risks associated with, and ensure effective use of, implantable devices in children and adolescents.

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development of safe and effective devices for children, and protect children during clinical studies.

FDA also

- recruits pediatric experts for its advisory panels when it seems likely that a device under discussion will be used for children
- helps develop effective surveillance of pediatric medical devices once the devices are approved for marketing
- collects data on the unmet needs of children, and identifies barriers to development of new products

Notable Examples

Noteworthy FDA-approved implantable pediatric devices include

The Medtronic Activa® Dystonia Therapy device

Indicated for use in children at least 7 years of age, this device treats dystonia, a debilitating condition characterized by involuntary muscle contractions. These contractions often produce twisting, abnormal postures, or repetitive movements. This device has an implanted pulse generator that is placed either under the skin of the abdomen or the collarbone and sends programmable electrical stimulation pulses to electrodes implanted in the brain.

The MED-EL COMBI 40 Cochlear Implant System

This system detects and recognizes sounds for people with severe hearing loss. It is approved for use in children between the ages of 12 months and

17 years and 11 months who have what is termed profound, bilateral sensorineural hearing loss. It is also approved for adults 18 years or older with the same condition who gain only limited benefit from conventional hearing aids.

Shunts

These devices move or allow movement of fluid from one part of the body to another. For example, shunts used in the brain divert excessive accumulation of cerebral spinal fluid to areas of the body where it can be absorbed. [FDA](#)

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For More Information

CDRH: Pediatric Medical Devices
www.fda.gov/cdrh/pediatricdevices/

Medtronic Activa® Dystonia Therapy device
www.fda.gov/cdrh/mda/docs/h020007.html

MED-EL COMBI 40 Cochlear Implant System
www.fda.gov/cdrh/mda/docs/p000025.html