Patient Safety and Medical Device Development

At Johnson & Johnson MedTech, keeping patients safe is always important.

A medical device is a product used to help prevent, find, watch, or treat health problems. Some devices are simple, like bandages. Others are more complex, like tools used in hospitals or during surgery. Common examples of medical devices include **contact lenses**, **knee replacements**, **blood pressure cuffs**, **inhalers**, **insulin pumps**, **hearing aids**, and **wheelchairs**.

Below are questions and answers about how we help keep patients safe before a device is used. The amount of testing and review depends on the type of device, what the device does, and how it will be used. **No matter what, patient safety comes first**. We understand that patients and families rely on medical devices every day, and patient safety guides every step of the process. This information is about medical devices in the United States, where the Food and Drug Administration, or FDA, helps protect public health by making sure these devices meet safety and quality standards.

What steps happen before a medical device is used?

Medical device development occurs in three main steps, with patient safety being the priority:

1. Understand the need

Purpose:

- Figure out what patients need and what the device should do.
- This often includes working with patients, doctors, nurses, and other healthcare providers to understand needs.

What Happens:

- Decide who will use the device and where it will be used (for example, at home or in a hospital).
- Plan the tests needed before the device can be used.

2. Build and test

Purpose:

- Design and build the device and make sure it works and is safe.
- This can include testing how people use the device and doing clinical studies to learn about safety and how well it works.

What Happens:

- Make the first version of the device and test how well it works.
- Safety experts review the results and help decide what changes are needed.

3. Review

Purpose:

- Help confirm that the device meets FDA requirements before it is made available.
- Prepare the device for patients.

What Happens:

- Share safety information and how well the device works with the FDA, if needed.
- Create materials to support safe use of the device.
- Provide training or educational materials to healthcare professionals, when appropriate, to help them use the device safely.

If I have more questions about J&J MedTech's approach to safety, where can I learn more?

For additional information please visit:
https://www.jnj.com/office-of-the-chief-medical-officer

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www.fda.gov
Individuals depicted are models, for illustrative purposes only.

Patient Safety after a Medical Device is Made Available

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We understand that patients and families rely on medical devices every day, and patient safety guides every step of the process. Below are key questions and answers about how we continue to prioritize patient safety even after the medical device is in use.

Once a device is being used, how does Johnson & Johnson MedTech help keep patients safe?

Our safety teams look for problems and protect patients. **They:**

Collect information from patients, doctors, nurses, and other healthcare providers about how the device is working and any problems they notice.

Review the information to see if the same problem keeps happening and if we need to take action to keep patients safe.

J&J MedTech follows all laws and regulations for collecting, reviewing, and sharing safety data after the device is available for use.

What happens if we find a problem after a device is being used by patients?

It depends on the problem. **We may:**

Correct the problem (for example, by changing the design). In some cases, we may STOP making the device available for use.

Update the label, instructions, or training so people know the latest safety information.

Send a letter with important safety information to doctors, hospitals, and patients.

Patients should speak with their healthcare provider about questions related to their care or use of a specific medical device, and follow the instructions provided with the device.

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