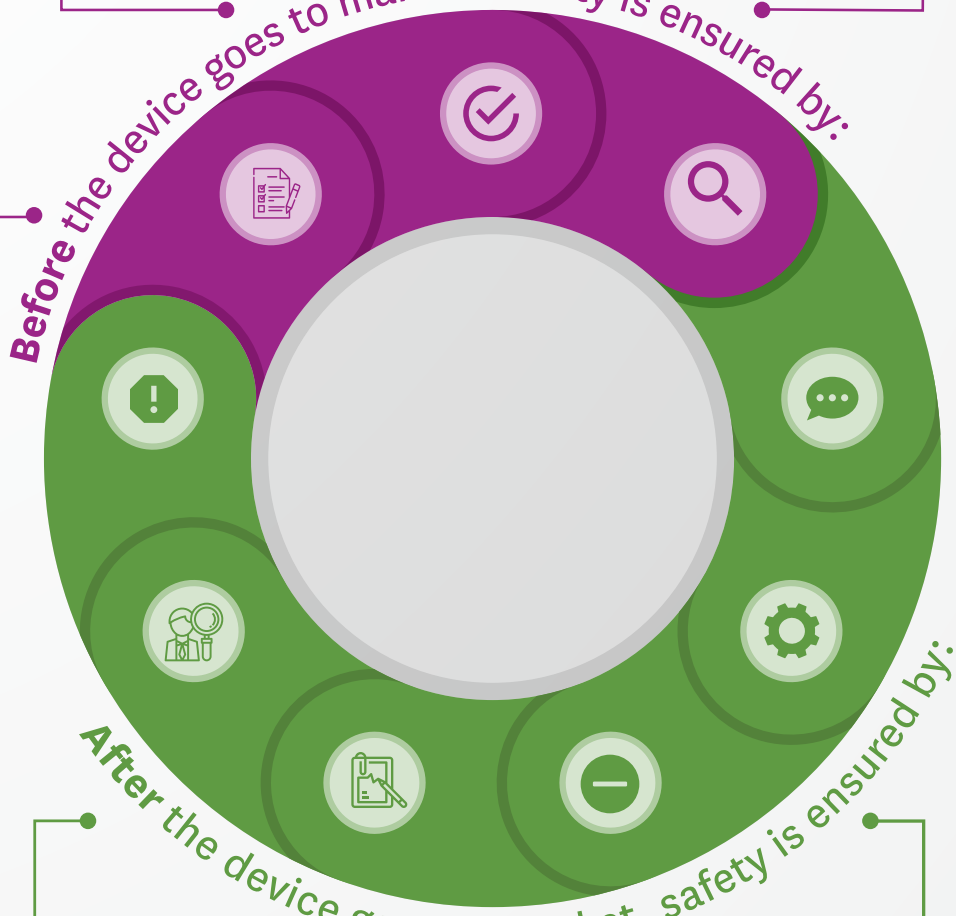
9 Touchpoints to Ensure Device Safety Across the Device Lifecycle

Patient safety is the medical device industry's #1 priority.

There are many protections in place to ensure that medical devices are safe. Please find a few of them below:



Device design requirements
design and test products to ensure safety and eliminate risks

Clinical testing
such as mechanical and computer testing and animal studies, including human testing for high-risk devices

FDA review
establishes a reasonable assurance of safety and effectiveness for the device

Complaint handling
companies must investigate complaints and file adverse event reports with FDA for serious injuries, deaths and device malfunctions

FDA regulatory action
FDA may seize products that pose safety concerns or prevent unsafe products from entering the U.S. DA may bar companies from distributing products that pose safety risks. Companies and their CEOs are subject to civil and criminal penalties if they violate product safety requirements

FDA inspections
FDA inspects companies to confirm that they meet safety requirements like proper device design, adverse event and recall reporting, and effective corrective and preventive actions

Recall reporting
companies must report to FDA when they fix devices or pull them from the market

Recalls and removals & Unique Device Identifier
companies regularly fix devices or pull them from the market to prevent possible safety concerns, even where there has been no actual harm. Each device must have a unique identifier to facilitate recalls and adverse event reporting

Corrective and preventive action
companies must investigate and fix products that do not perform as intended and prevent product failures. Companies must verify that these actions are effective