MEDICAL DEVICE SOLUTIONS

Ensure safety and compliance with machine vision, AI, barcode reading, and barcode verification solutions
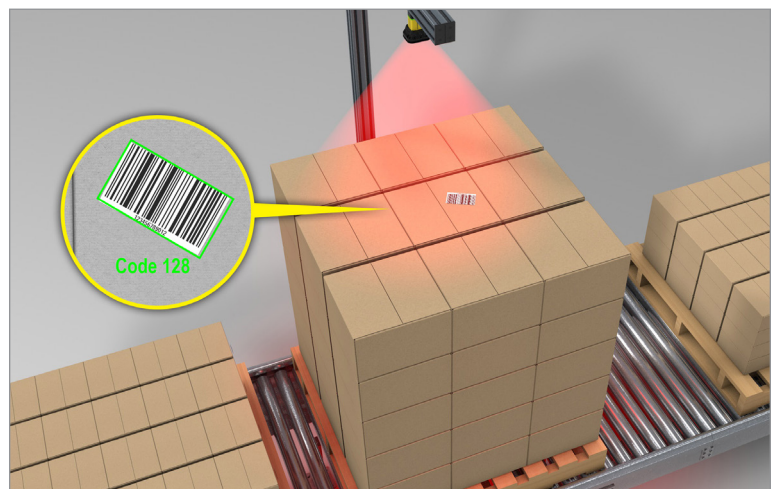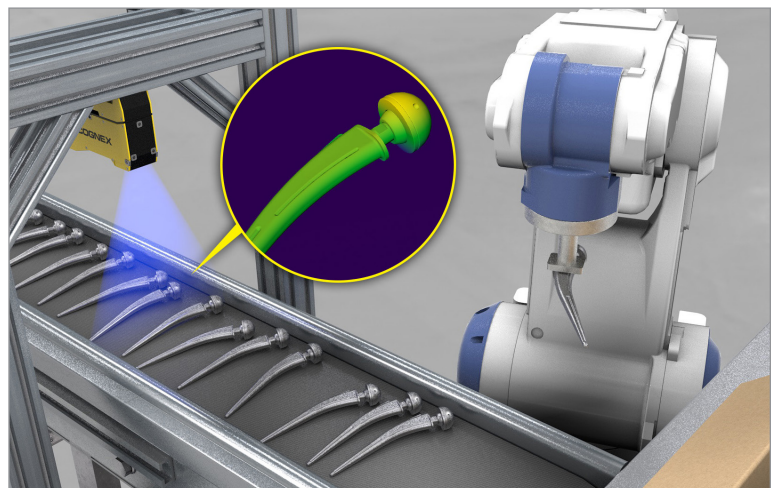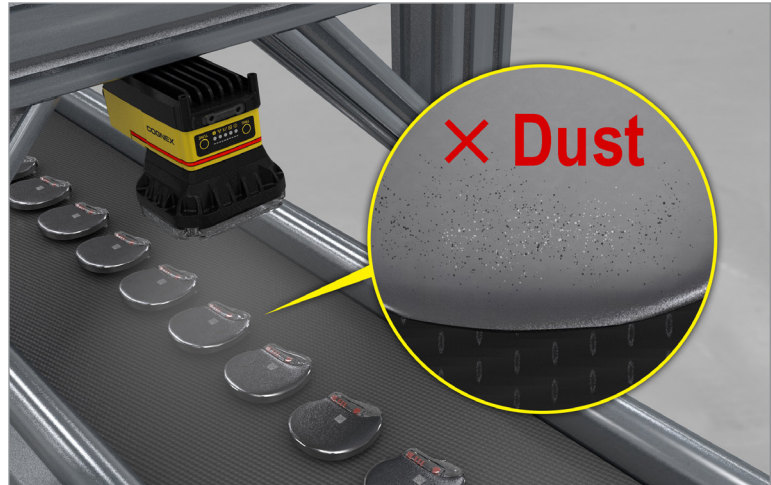
COGNEX

ENSURE SAFETY AND COMPLIANCE
WITH COGNEX TECHNOLOGY AND SOLUTIONS

The United States Food and Drug Administration (FDA) Unique Device Identifier (UDI) mandate and the European Commission Medical Device and In Vitro Diagnostic Regulations (MDR/IVDR) require the use of UDI systems to trace medical devices through the supply chain. The goal of the UDI initiative is to provide a foundation for safe and secure global distribution of the various classes of medical devices.
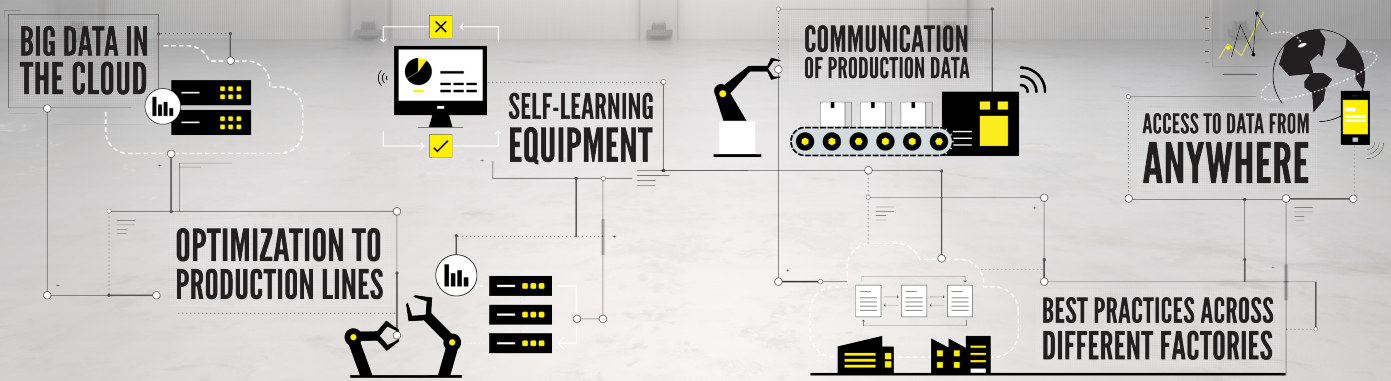
Properly marking and registering medical devices provides a faster method to identify faulty, recalled, or expired products. It also helps address issues such as counterfeiting and gives doctors and patients more confidence in the quality of the products used. Even in the absence of regulations, medical device manufacturers need solutions that minimize the production of unsafe products and reduce costly product recalls.

Machine vision, AI, barcode reading, and barcode verification technology help automate part and marking inspections, code reading, and code quality while ensuring medical device safety and compliance.

DIGITALIZATION
AND SELF-REGULATION

BIG DATA IN THE CLOUD

SELF-LEARNING EQUIPMENT

COMMUNICATION OF PRODUCTION DATA

ACCESS TO DATA FROM ANYWHERE

OPTIMIZATION TO PRODUCTION LINES

BEST PRACTICES ACROSS DIFFERENT FACTORIES

Industry 4.0 is driving change in the packaging industry as manufacturers seek to capitalize on emerging innovations in advanced automation. Machine vision, Big Data, cloud computing, and machine learning are revolutionizing manufacturing processes. Moving along the journey to Industry 4.0 presents an opportunity to digitalize processes that bolster productivity, reduce waste, improve product quality, enhance manufacturing flexibility, and decrease operating costs. Implementing a digitalization strategy also presents an opportunity to address ongoing labor shortage challenges.

As Industry 4.0 compatible edge systems and devices, Cognex machine vision and AI-based solutions create valuable digital data that serves two purposes. First, these systems capture real-time information such as inspection and measurement data that facilitates automatic in-line quality decisions. In addition, companies see great value in either feeding this data back into the process in real time or aggregating this data over time, performing off-line analytics, and using the resulting insights to drive process improvement and predictive maintenance. Cognex vision systems facilitate the digitalization of quality control processes through easy integration into industrial networks via standard communication and file transfer protocols such as TCP/IP, PROFINET, EtherNet/IP, SLMP, OPC/UA, and FTP.

SAMPLE USE CASE

Many medical device products must be properly sealed to protect sterility. There are a wide variety of defects, such as underseals, overseals, voids, and foreign material that if missed, can cause contamination and product recalls. These defects can be caused by various issues with sealing machines, such as improper or uneven heating or misalignment of the sealing material to the backing. Given the variety of production issues that can occur, it is challenging to maintain consistent product quality without detailed inspection results data.

To overcome this challenge, a machine vision or AI-based system can provide inspection data in a closed loop process with the sealing machine so it can automatically respond to specific defects by adjusting machine parameters in real time.
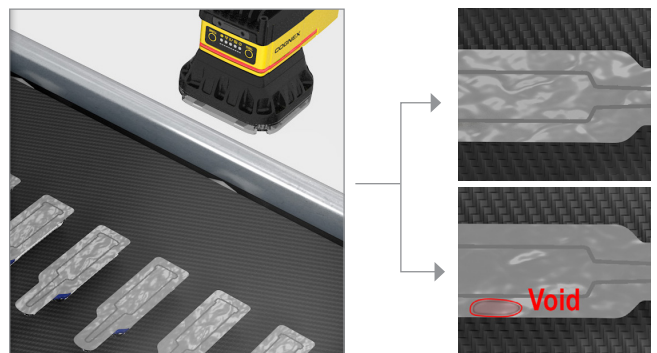
MEDICAL DEVICE
PART INSPECTION

Medical devices come in many complex shapes, sizes, and materials, from a shiny metal knee replacement to the small webbing of a stent. Because medical devices are used on or implanted inside the human body, quality inspection of the part is critical. Machine vision and AI-based solutions help identify microscopic surface defects, scratches, dents, or contamination that could be harmful to a patient.

## Surgical Equipment Gauging
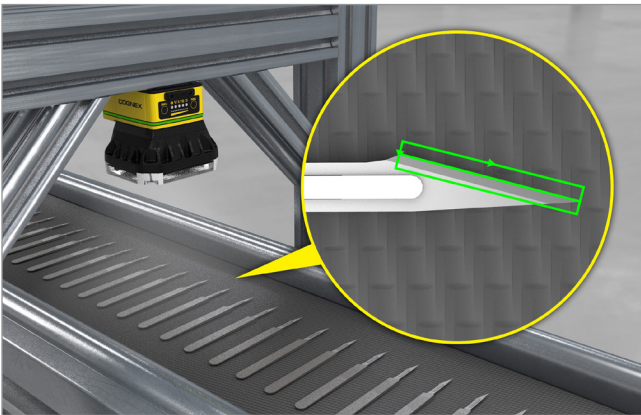
Gauging, measuring, and ensuring high quality standards is an integral part of the medical device manufacturing processes. In order to comply with rigorous quality standards, Cognex vision systems provide high accuracy and repeatability.

Hip Replacement Defect Detection
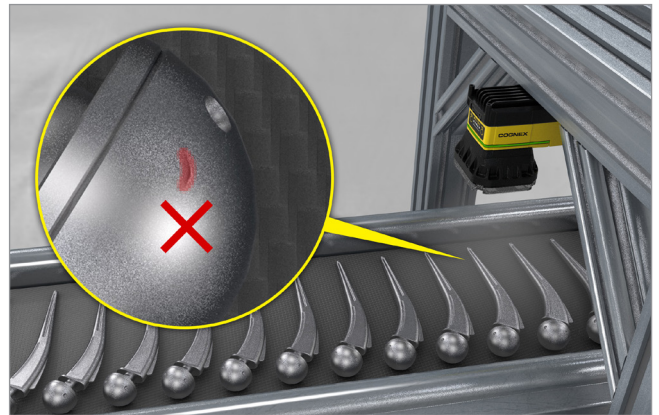
AI-powered image analysis software detects defects on metal surfaces of knee or hip replacements as reliably as human inspectors, but with the speed of a computerized system.

Stent Webbing Inspection
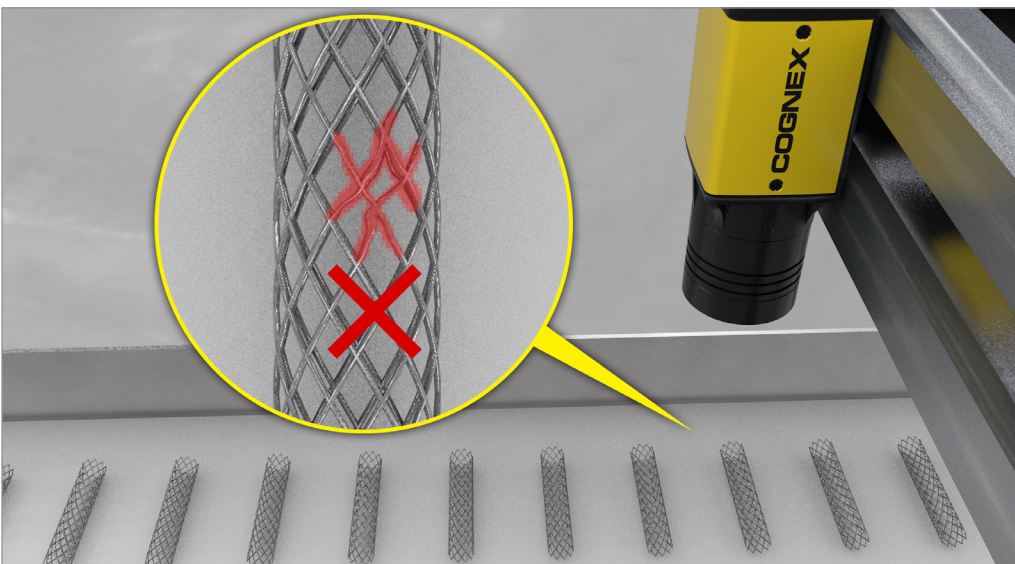
Stent quality is notoriously challenging to solve with traditional machine vision because of complex geometries and materials. AI-based technology understands complex shapes and patterns and can correctly identify abnormalities.

Contamination Detection
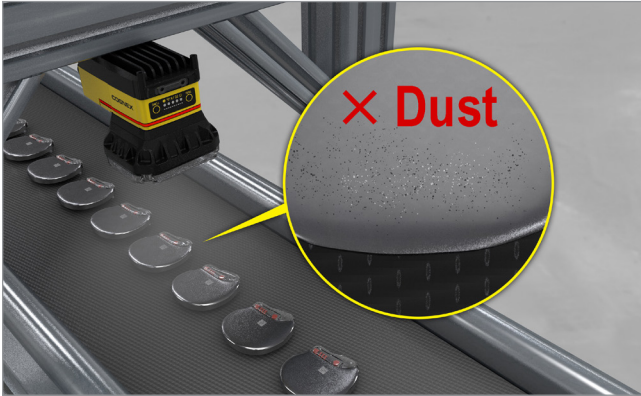
Contamination can occur at any stage of the manufacturing process and is hard to catch on medical device parts. AI-enabled solutions can detect contaminated surfaces such as dust on a pacemaker.

Face Mask Quality Control Inspection
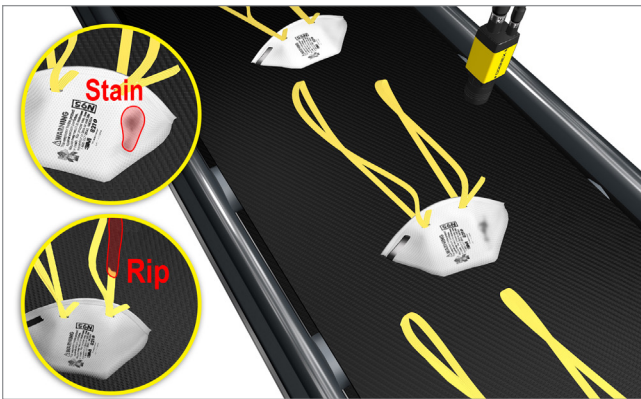
Cognex AI-powered technology inspects face masks for random defects, such as rips, stains, and stitching errors to rigorous quality standards.

Transdermal Patch Inspection
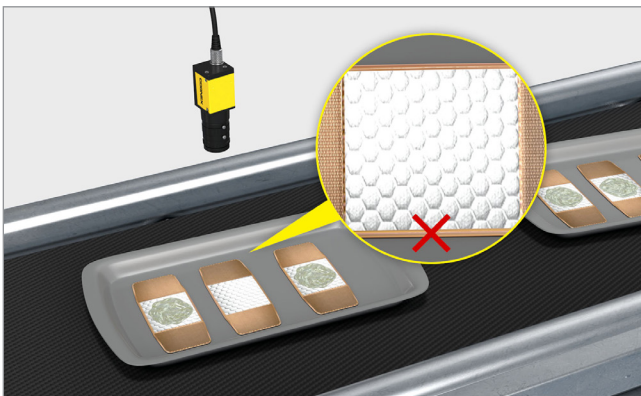
Transdermal patches are checked for accurate dosages of active medical ingredients using AI-based technology before packaging.
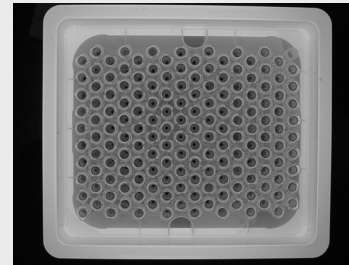
Advanced Image Formation Technology

High Dynamic Range Plus (HDR+) is a patent-pending technology that delivers a high-contrast, uniform image in a single acquisition for multi-point inspections of parts with varying depths of field and lighting conditions.
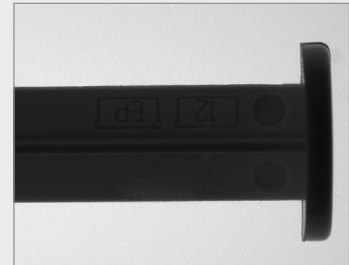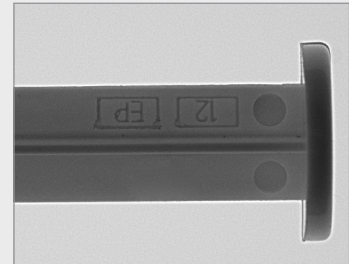
Conventional Sensor
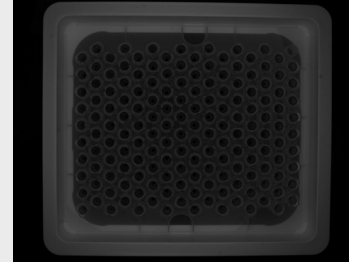
HDR+

Conventional Sensor

HDR+

UDI MARKING
AND QUALITY INSPECTION

UDI marks include device and production identifiers with important information like lot number, serial number, manufacture and expiration dates. The mark must be readable and decipherable throughout the device lifecycle to maintain compliance. Machine vision and AI-based solutions verify that codes and text are present and accurately formatted. Barcode verifiers ensure codes meet quality standards.

DPM Code Quality Inspection and OCR

Maintaining UDI compliance is critical. Machine vision systems equipped with OCR technology verify that UDI codes are present and marked correctly.

Label-based Verification on Packaging
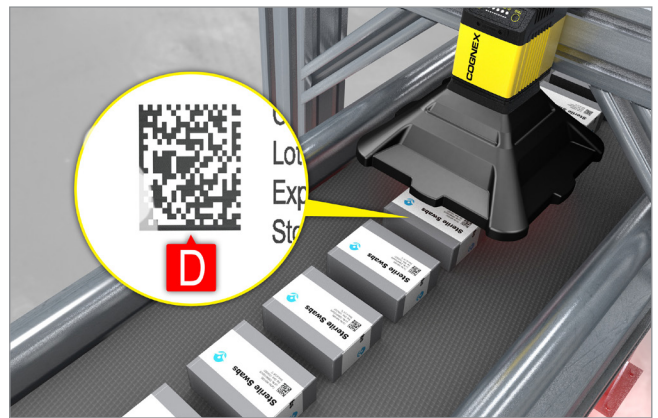
Inline barcode verifiers grade the quality of label-based barcodes on medical device packaging to ensure they meet quality standards.

Challenging OCR Code Reading
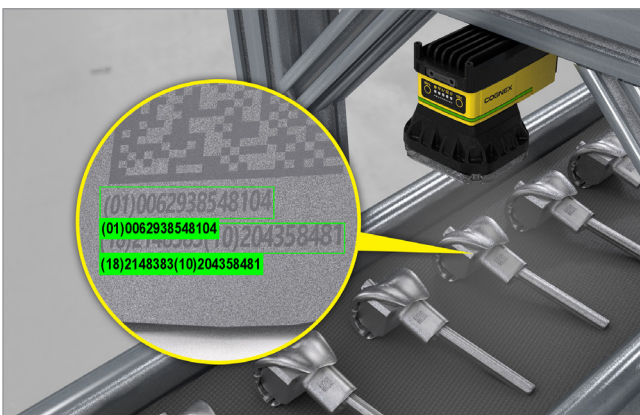
For challenging OCR codes including laser-engraved or chemically-etched DPM text, AI-enabled OCR tools read and verify that the chain of numbers and letters is correct.

DPM Code Verification on Metal Parts
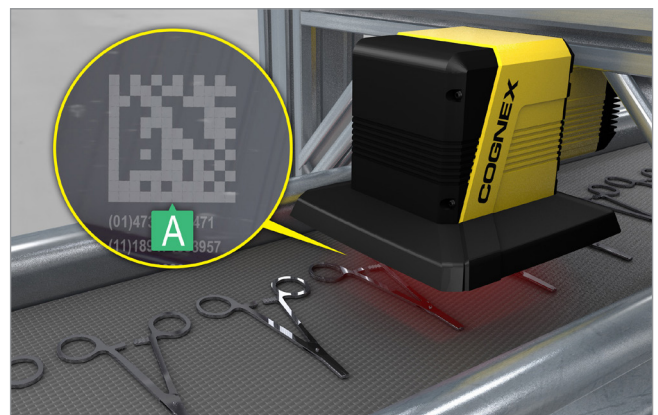
Readability of direct part mark codes on medical device parts requires verification of symbol quality with ISO-compliant barcode verifiers.

MEDICAL DEVICE
TRACEABILITY

After the marking or label printing process, codes can be low contrast or damaged, recessed, marked on shiny or white surfaces, or printed under shrink-wrap that makes them hard to track and trace. Image-based barcode readers and machine vision OCR technology can ensure medical devices of all shapes and sizes are properly scanned and can be easily identified and located in the event of a product recall.

TRACK: Where is it now?

TRACE: Where has it been?

CONTROL: Where is it going?

Laser-Etched Barcode Reading

Handheld barcode readers decode small laser-etched codes on shiny and cylindrical surfaces like those found on medical instruments and artificial implants such as a replacement hip or knee.

High-Speed Barcode Reading Under Shrink Wrap

Fixed-mount barcode readers decipher label-based codes quickly and reliably on high-speed lines, even under shrink-wrap.

Multiple Barcode Reading

With large depth-of-field and wide field-of-view coverage, Cognex barcode readers combined with High-Speed Steerable Mirror technology read multiple codes simultaneously.

Optical Character Recognition (OCR)

Machine vision systems with OCR technology reliably read alphanumeric date/lot codes throughout the supply chain.

PACKAGE INTEGRITY
AND STERILITY

Package, label, and seal integrity are critical to ensure packaging is correct, sterile, and contaminant-free when heading into a doctor's office or operating room. Machine vision and AI-based solutions check for bubbles or punctures and reliably identify foreign objects, void seals, and a host of other issues that can impact medical device package integrity and sterility.

Seal Inspection with AI
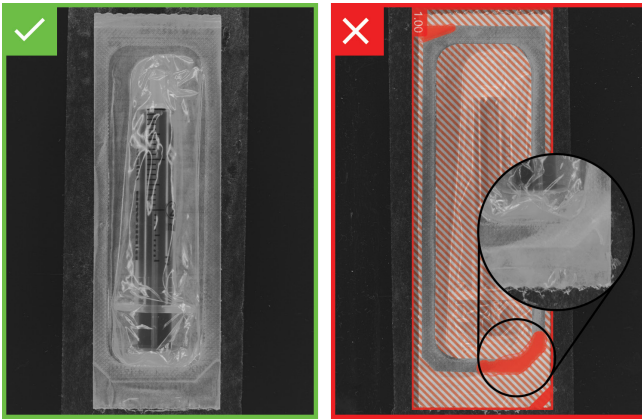
Seal inspection has previously been a complex and expensive process using ultrasonics and operators to find defects. AI-based technology resolves complex issues such as underseals, overseals, voids, and foreign material to avoid contamination and product recalls.

Seal Inspection with 3D Vision
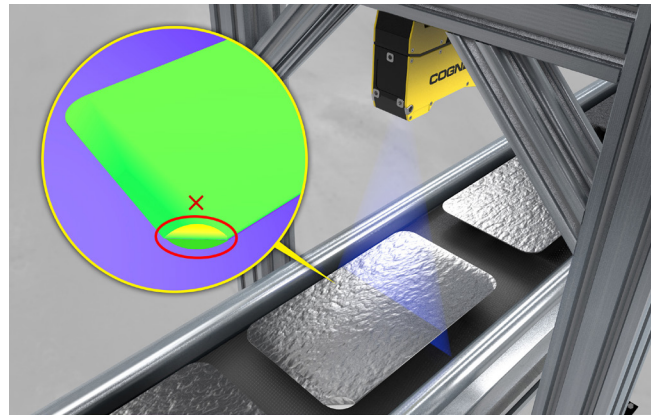
Cognex 3D solutions ensure even and consistent final packaging either during or at the end of a medical device packaging process.

Defect and Contamination Detection
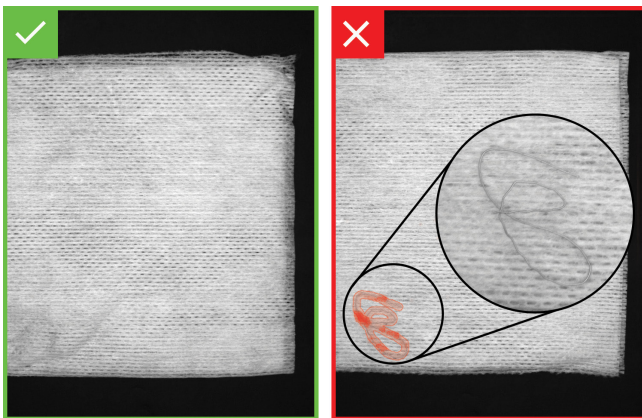
AI-powered technology allows medical device manufacturers to capture cosmetic defects in real time before shipment. This includes white on white anomalies and other hard to capture defects previously impossible to inspect using traditional vision technology.

Package and Label Integrity Inspection

AI-enabled image analysis software detects packaging defects, bubbles in labels, torn labels, and other package integrity and cosmetic defects that could otherwise result in device mix-ups or scrappage.

# PACK ASSEMBLY
AND KIT INSPECTION

Kitting or system and procedure pack applications must verify that the correct item is in the correct location of a kit and confirm the presence or absence of items. Regulations also require patient implant cards, directions, and/or caution documents to be included in the assembly. Machine vision and AI-based solutions verify that all medical devices and other items are present and accurate, even under shrink-wrapped packaging.
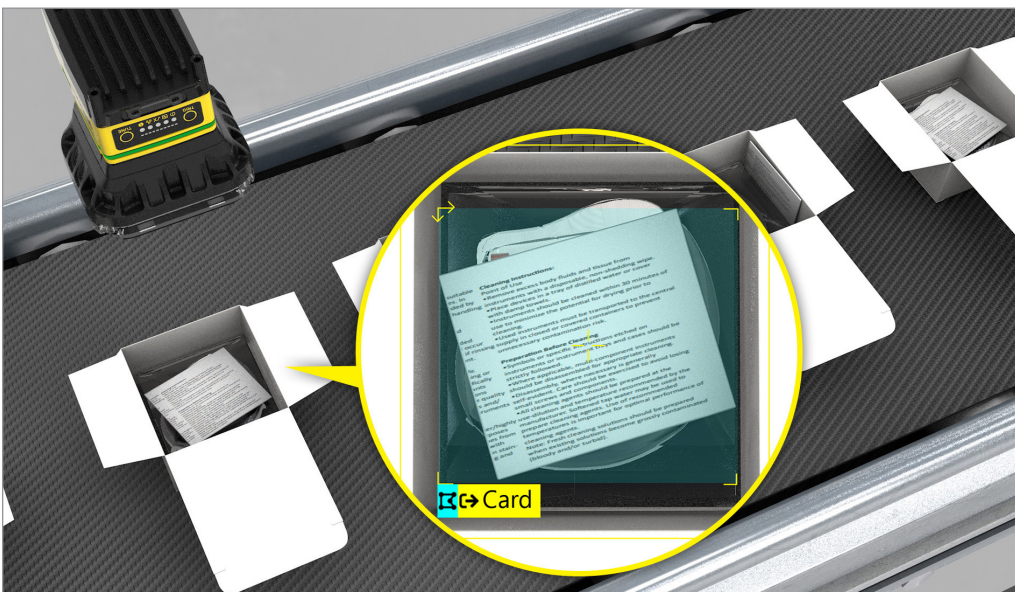
Medical Kit Assembly Verification

AI-enabled systems count, ensure proper orientation, and maintain correct quantities for a number of kit assembly applications, from syringe sets to medical device components.

Vaccine Kit Assembly Verification
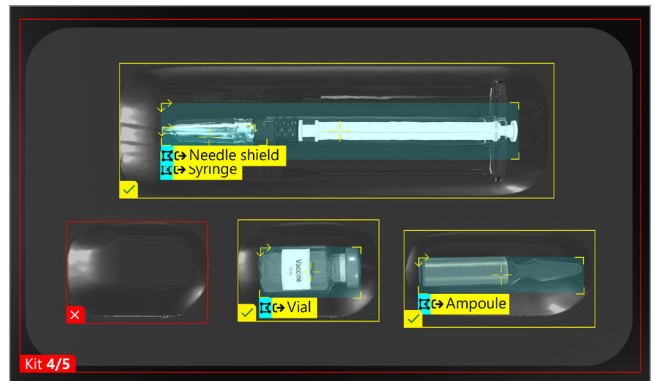
AI-powered solutions inspect vaccine kits for overlapping or missing parts and ensure the correct parts are present and in the right orientation.

Patient Implant Card Confirmation

Cognex AI-based technology reliably locates and identifies the insert in boxes regardless of orientation and lighting conditions to prevent recalls and ensure patient safety.

Final Assembly Verification

Completed and packed medical and drug kits made up of several parts are checked for completeness and damage through x-ray inspection combined with AI-based technology immediately before shipping.

Drug Delivery Device Final Assembly Verification
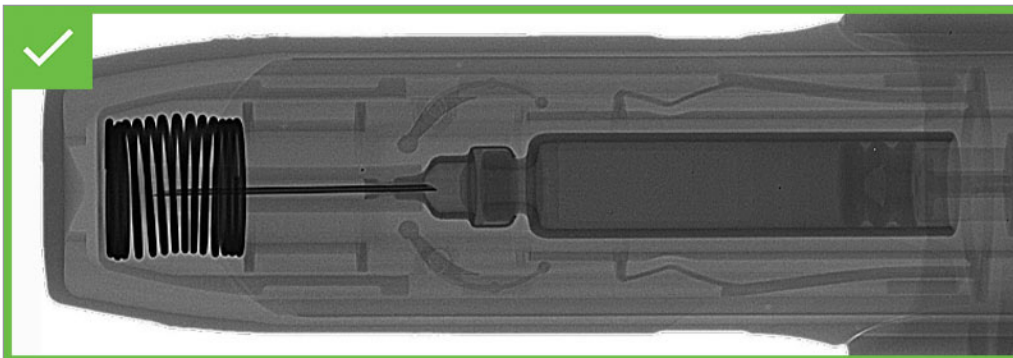
Cognex AI-enabled solutions ensure device completeness and functionality after packaging.
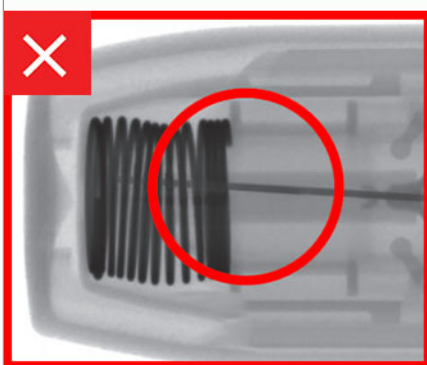
PACK AGGREGATION
AND PALLETIZATION

In preparation for shipping, kits are aggregated into cases according to specific orders and then put on pallets. The accuracy of the case contents must be verified, and any missing items identified. Image-based barcode readers and vision-guided robotics are able to read multiple codes at one time in a large field of view and perform advanced inspections for reliable pack confirmation.
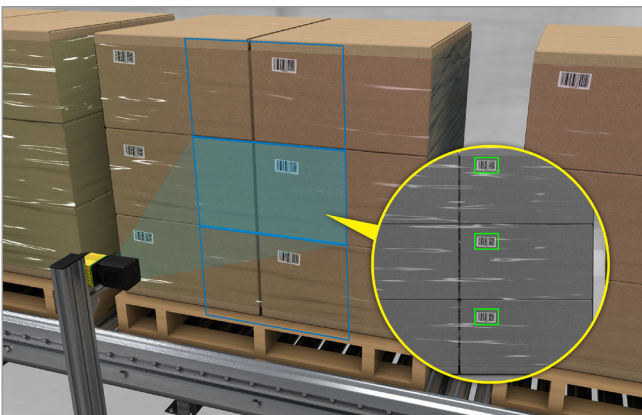
Robotic Case Packing
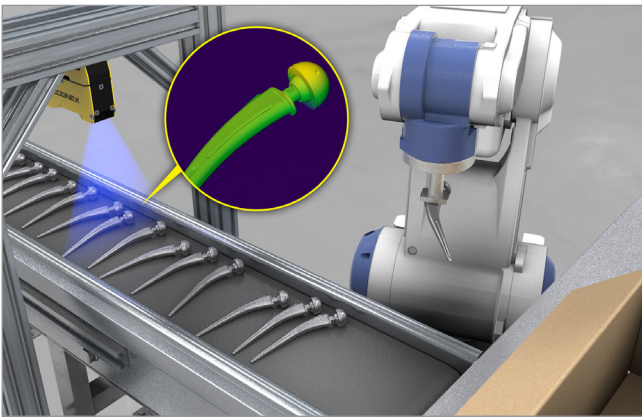
Packing objects with complex geometries can be very challenging. Cognex 3D toolsets communicate to robots for easy case packing.

Robotic Palletization
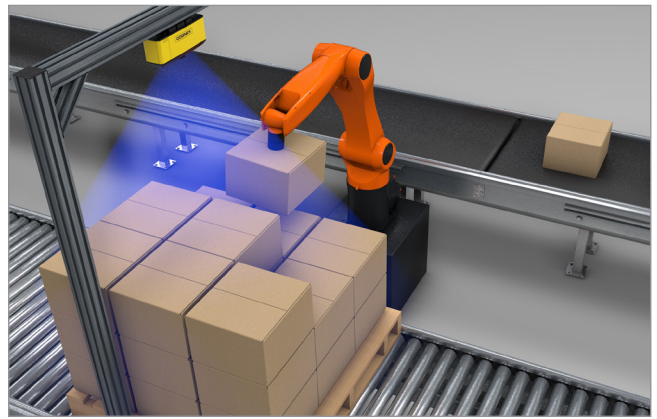
Vision-guided robotics palletizes cases for distribution, eliminating the need to physically handle the products and risk contamination.

Multiple Barcode Reading on Pallets

Cognex has optimized and engineered specific multi-barcode reading and vision systems to manage wide fields of view with high read rates for inbound and outbound pallets.

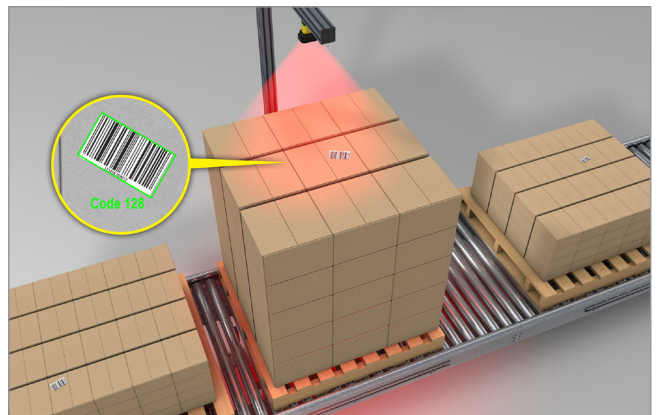## Large Depth of Field Barcode Reading

Image-based barcode readers with high-powered integrated torch light adapt to changes in pallet heights and ensure codes are read quickly and accurately.

COGNEX AI

Cognex AI learns to spot patterns and anomalies from example images. It solves tasks that are too complicated and time-consuming to program with rule-based algorithms, while providing a consistency and speed that aren't possible with manual inspection.

Edge learning: Designed for ease of use

Edge learning is a subset of AI in which processing takes place on-device, or "at the edge," using a pre-trained set of algorithms. The technology is simple to setup, requiring smaller image sets and shorter training and validation periods than traditional deep learning-based solutions.
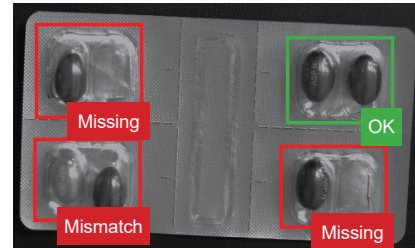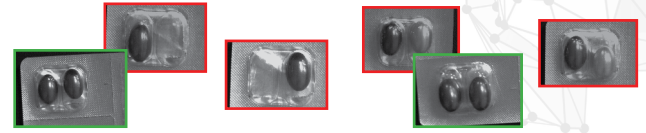
## Deep learning: Designed for complex applications

Capable of processing large, detailed image sets, deep learning is designed to automate complex or highly customized applications. The technology enables users to analyze vast image sets quickly and efficiently, while differentiating between acceptable and unacceptable anomalies, to deliver accurate results.
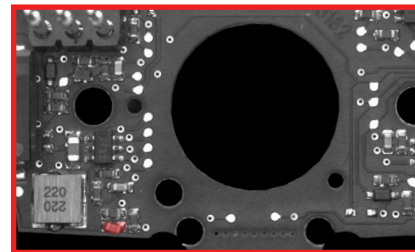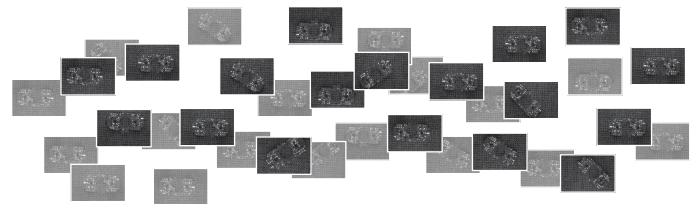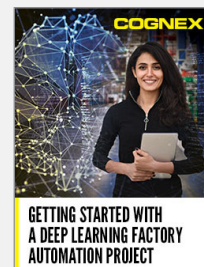

Cognex AI resources

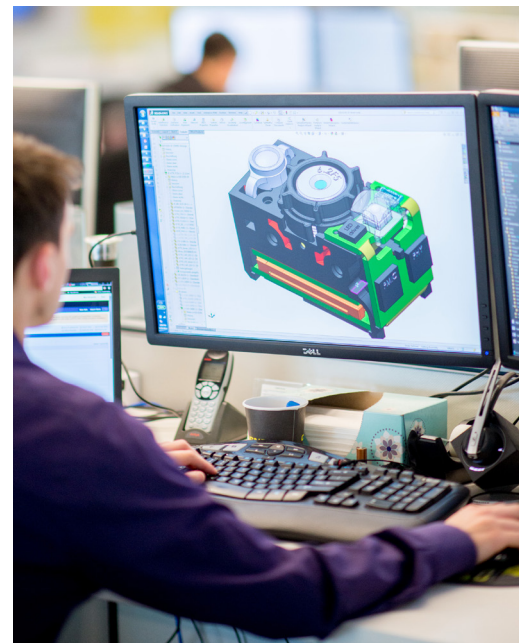**Watch** *Machine, Deep, or Edge Learning: What's the Difference?*
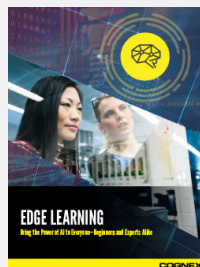
Read *Edge Learning: The Power of AI for Everyone*

Read *Getting Started with a Deep Learning Factory Automation Project*

COGNEX GLOBAL SERVICES

Technical Support ▪ Product Training ▪ Self-Service Portal ▪ Lifecycle Management

Cognex serves an international customer base from offices located throughout the Americas, Europe, and Asia and through a global network of highly-trained partners, system integrators, and distributors.

From development to deployment, Cognex is there to get your vision systems up and running as fast as possible. Whether you're considering machine vision for the first time or are already an expert user, Cognex global services provide the expertise to help your organization succeed.

www.cognex.com/support/cognex-services
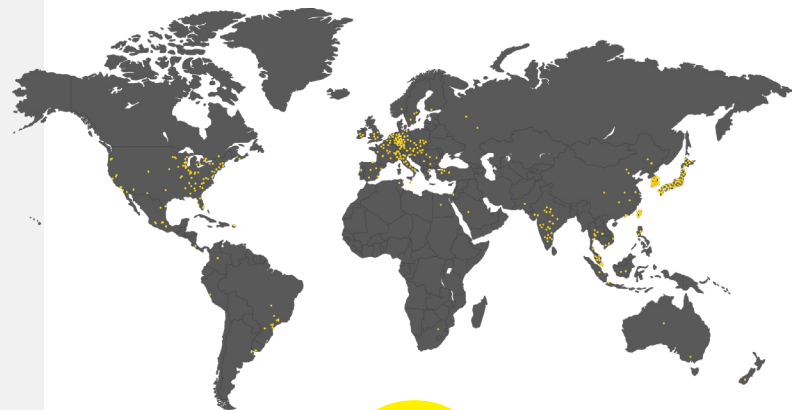
Offices in **20+** countries

500+ Global partners in 30 countries

Medical Device Solutions

THE GLOBAL LEADER
IN MACHINE VISION AND BARCODE READING

For over 40 years, Cognex has helped the world's most innovative companies make their manufacturing and distribution faster, smarter, and more efficient.

Cognex vision systems and barcode readers help customers improve product quality and operational performance by eliminating defects, verifying assembly, and tracking information at every stage of the production process. Using data captured by Cognex vision systems and barcode readers, companies can monitor, update, and change production plans in real-time across global supply chains.

Smarter automation using Cognex products means fewer errors, which equates to lower costs and higher customer satisfaction. And Cognex is constantly applying new techniques, like artificial intelligence, to enable companies to evolve their automation strategy to meet today's and tomorrow's needs.

With a wide range of solutions and a large network of global vision experts, Cognex makes it possible to **Build Your Vision.™**
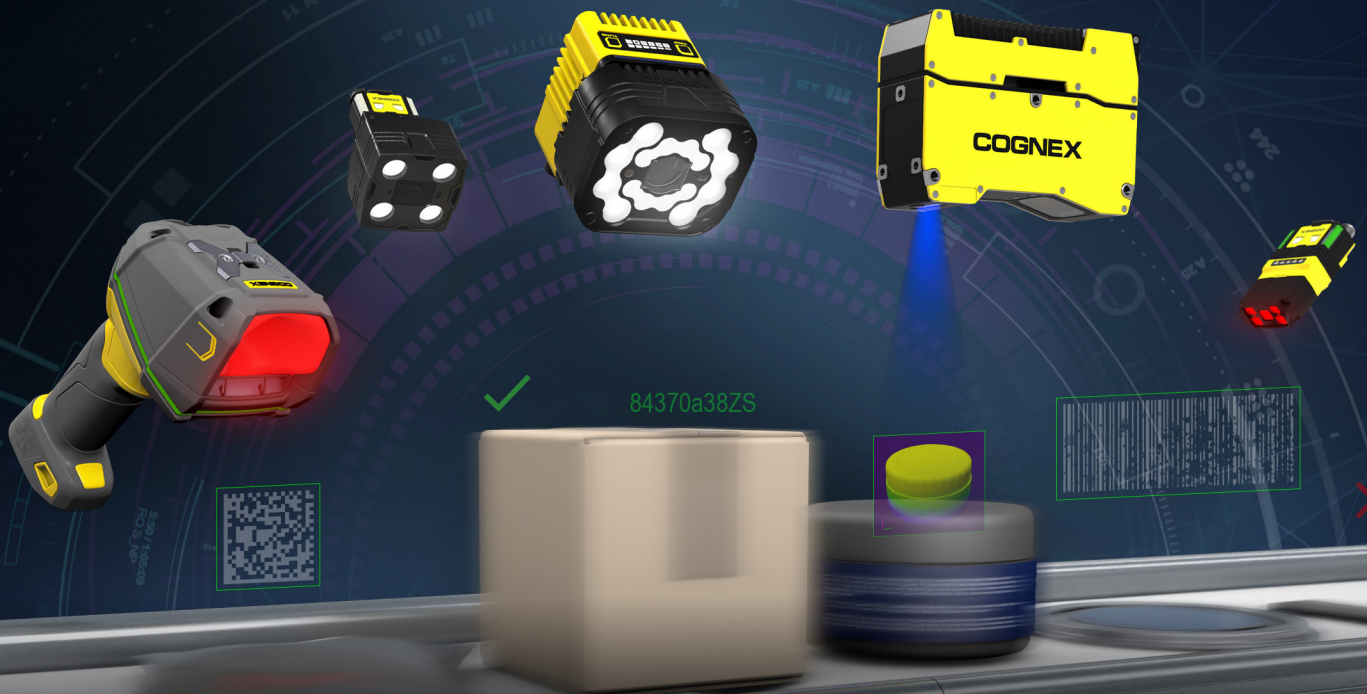
$1 BILLION
2022 REVENUE

OVER 42
YEARS IN THE BUSINESS

500+
CHANNEL PARTNERS

GLOBAL OFFICES IN
20+ COUNTRIES

4,000,000+
SYSTEMS SHIPPED

84370a38ZS

BUILD YOUR VISION

Vision Systems

Automate inspection tasks, from defect detection to assembly verification and text reading, with easy to deploy vision systems.

www.cognex.com/machine-vision

Barcode Readers

Track and trace, from the floor to dock door, with powerful readers and verifiers designed to handle any code type.

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Industry Solutions

Solve applications across a wide range of industries with flexible and reliable machine vision and barcode reading solutions.

www.cognex.com/solutions

COGNEX

Companies around the world rely on Cognex vision and barcode reading solutions to optimize quality, drive down costs and control traceability.

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