

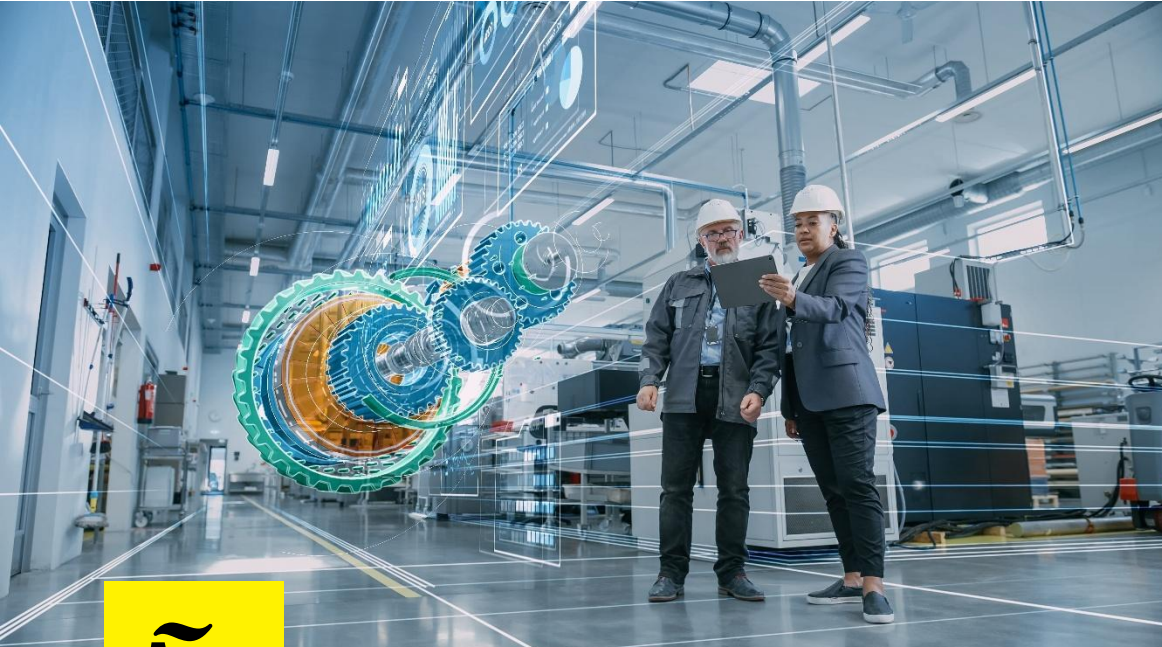


# Seeing Clearly: A Practical Framework for AI & Machine Vision in Medical Manufacturing

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# The Core Challenge: The Limits of Yesterday's Quality Control



**Current inspection methods are struggling to keep pace with modern manufacturing demands.**



**We face two fundamental challenges with our established quality control processes:**

## **The Human Limit:**

It is incredibly taxing for humans to visually inspect small and microscopic items. The work strains the eyes and makes inspectors prone to missing critical defects that can impact patient lives.

## **The Validation Hurdle:**

Traditional vision systems are difficult to install and take too long to validate. The validation process after a new line is installed can take an immense amount of time. One of our customers reported it took their team two years to validate a system to meet internal and FDA standards. This is a major bottleneck to innovation and speed-to-market.

# The Solution: Why Top Manufacturers are Turning to AI-enhanced Vision



AI-enhanced vision directly addresses these challenges and unlocks new strategic advantages.



**To Meet Mandated Compliance & Traceability:** Regulatory requirements, like the Unique Device Identifier (UDI) rules, mandate robust traceability systems. This is essential for preventing counterfeit items and facilitating easier product recalls. To maintain compliance, UDI marks must be readable and decipherable throughout the entire device lifecycle.



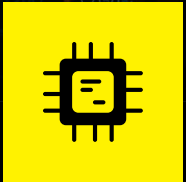
**To Boost Operational Efficiency & Flexibility:** The technology enables faster automation and shorter changeover times. This allows manufacturers to handle a variety of products, custom packaging, and unusual package forms with ease, ultimately bolstering productivity, reducing waste, and decreasing operating costs.



**To Unlock Data for Process Intelligence:** These systems create valuable digital data that serves two purposes.

- They provide real-time information for in-line quality decisions.
- This data can be fed back to machinery for real-time adjustments or aggregated for off-line analytics to drive process improvement and predictive maintenance.

# A Practical Framework to Implementing Vision With AI



**How to Make  
AI Vision a Reality.**

**01**

## **The "Why":**

The Strategic Imperative for Automated Inspection.  
(We just covered this).

**02**

## **The "What":**

Real-World AI-enhanced Vision Applications Across  
the Product Lifecycle.

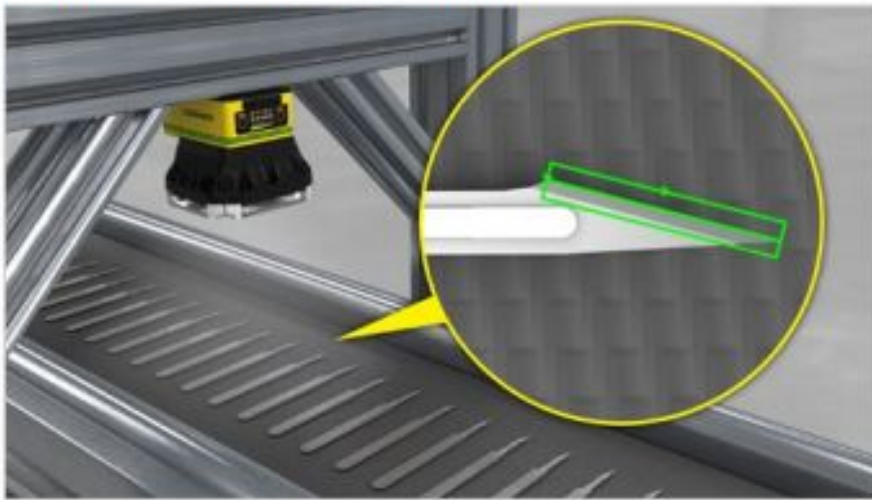
**03**

## **The "How":**

A Clear Path to Successful Deployment.

# Application 1: Flawless Component Inspection 1/4

## 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.



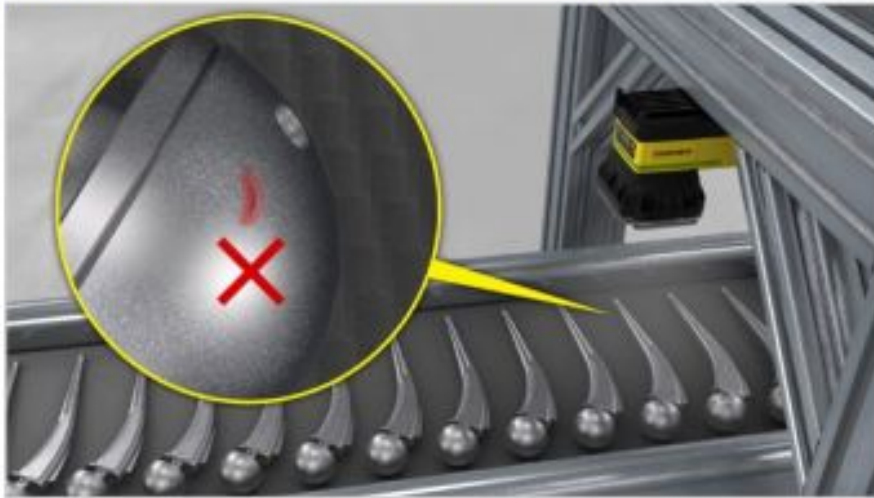
## Achieving Perfection at a Microscopic Level.

Patient safety begins with a flawless device.

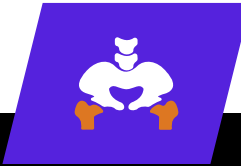
AI can identify defects on challenging surfaces that traditional systems miss

# Application 1: Flawless Component Inspection 2/4

## 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.

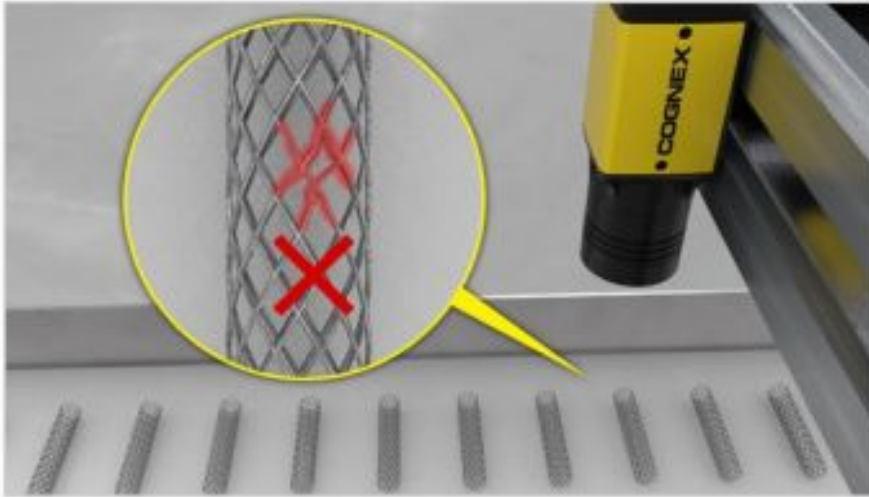


## Hip Replacements:

AI detects subtle scratches and defects on highly reflective, curved metal surfaces with the reliability of a human inspector but at the speed of an automated system.

# Application 1: Flawless Component Inspection 3/4

## 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.

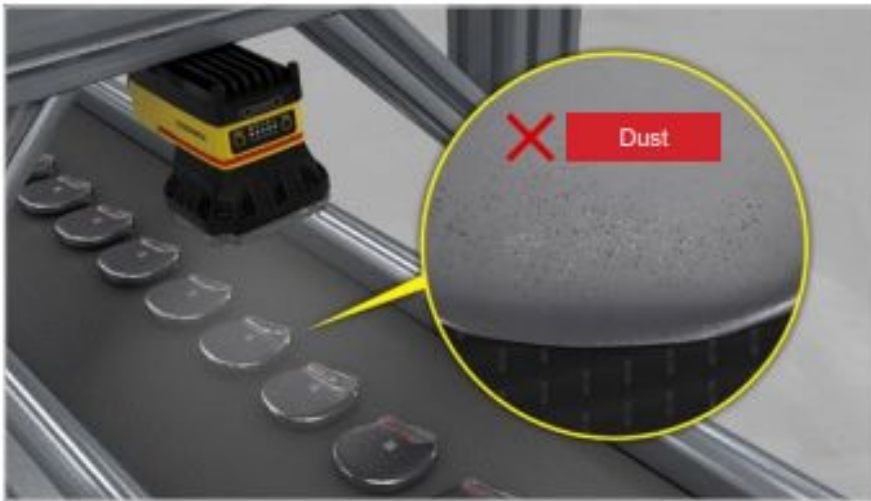


## Stents:

AI is uniquely suited to inspect complex geometries like stent webbing for abnormalities, a task that is notoriously difficult for traditional vision.

# Application 1: Flawless Component Inspection 4/4

## 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.



## Contamination:

AI-enabled solutions can detect microscopic contaminants, like dust on a pacemaker, before it's packaged.

# Application 2: Guaranteeing Kit & Pack Accuracy



## Medical Kit Assembly:

AI systems can instantly verify that a kit contains the correct items—cold pack, gauze, aspirin—and flag any missing components.



## Vaccine Kits:

For complex assemblies, AI inspects for overlapping or missing parts like vials, syringes, and ampoules to ensure the kit is complete and correct.



## Patient Implant Cards:

Vision systems can confirm that critical documentation, like implant cards, is included in the final package to meet regulatory requirements and ensure patient safety.

## Pack Assembly and Kit Inspection

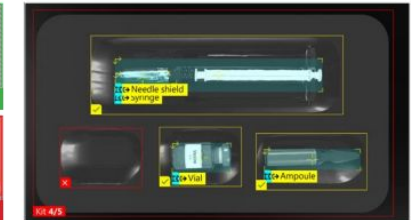
Kitting or system and procedure pack applications must verify that the correct item is in the correct location of a kit and confirm the presence or absence of items. Regulations also require patient implant cards, directions, and/or caution documents to be included in the assembly. Machine vision and 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.

# Application 3: Ensuring Package Integrity & Sterility



Packaging failure is a patient safety failure. AI provides a new level of certainty that sterile barriers are uncompromised.



**AI-Powered Seal Inspection:** Instead of complex and expensive ultrasonic methods, AI can visually inspect seals for underseals, voids, or trapped foreign material to prevent contamination and recalls.

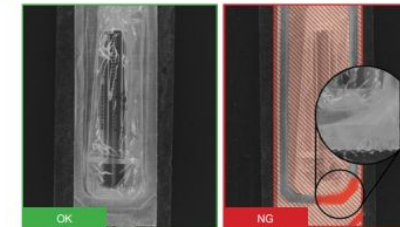


**Cosmetic Defect Detection:** AI can even find "white on white" anomalies, like bubbles or tears in labels, that could lead to device mix-ups or scrappage.

## Package Integrity and Sterility

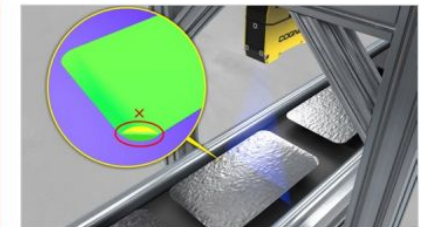
Package, label, and seal integrity are critical to ensure packaging is correct, sterile, and contaminant-free when heading into a doctor's office or operating room. Machine vision and AI-based solutions check for bubbles or punctures and reliably identify foreign objects, void seals, and a host of other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

### Seal Inspection with AI



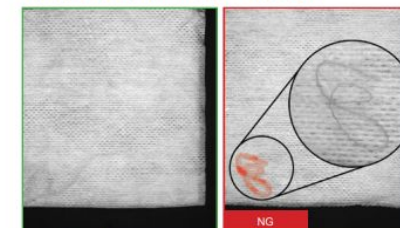
Seal inspection has previously been a complex and expensive process using ultrasonics and operators to find defects. AI-based technology resolves complex issues such as underseals, overseals, voids, and foreign material to avoid contamination and product recalls.

### 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



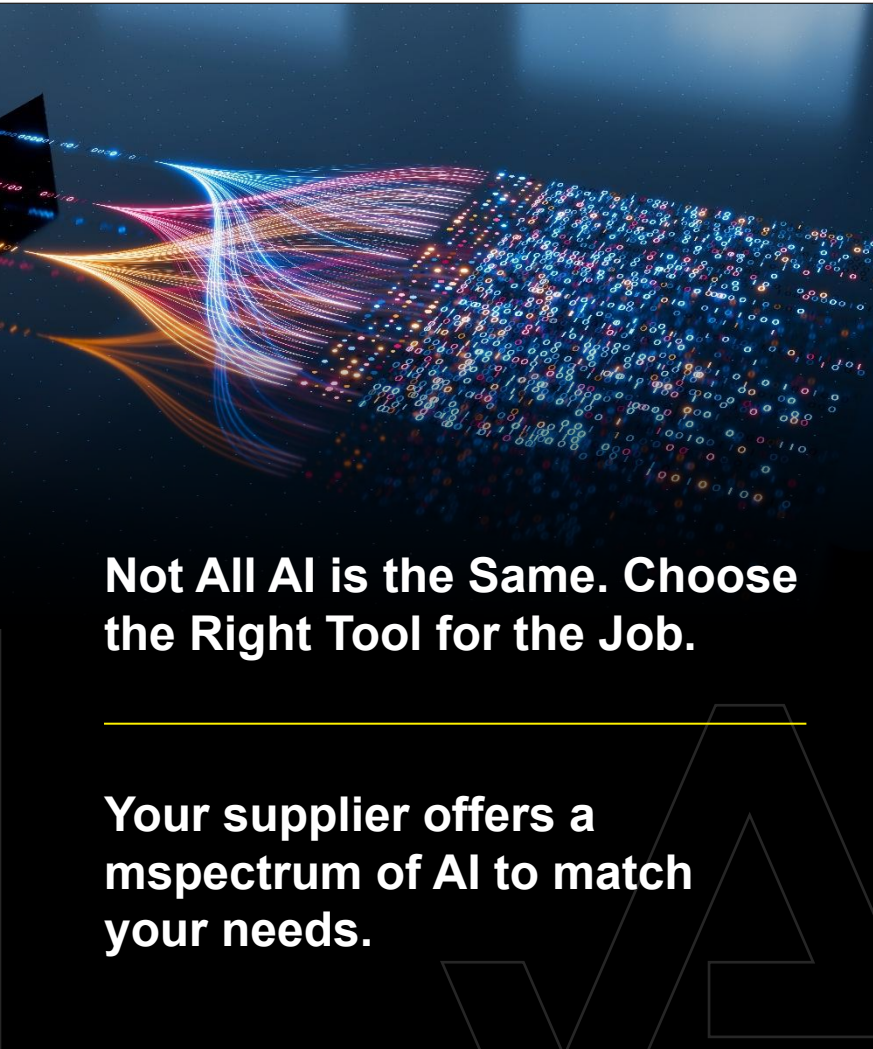
AI-powered technology allows medical device manufacturers to capture cosmetic defects in real time before shipment. This includes white on white anomalies and other hard to capture defects previously impossible to inspect using traditional vision technology.

### Package and Label Integrity Inspection



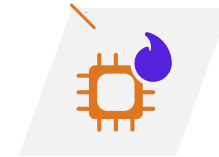
AI-enabled image analysis software detects packaging defects, bubbles in labels, torn labels, and other package integrity and cosmetic defects that could otherwise result in device mix-ups or scrappage.

# The Technology: Two Paths to AI Deployment



## Edge Learning:

For more straightforward tasks. It's designed for ease of use, requires smaller image sets, and can be set up quickly right on the device. Think of it as "out-of-the-box" AI.



## Deep Learning:

For your most complex and customized applications. It analyzes vast image sets to deliver incredibly accurate results for highly nuanced problems. This is for the challenges you thought couldn't be automated.

# A Practical Framework for Implementation

## How to Get Started: A 3-Step Approach.

### Evaluate:



Start with the business case. Identify the top sources of waste, risk, or manual labor cost. **Any where you have people's eyes inspecting a part – a camera could do a better job.** Don't automate for automation's sake; target the areas with the highest ROI.

### Validate:



Run a proof-of-principle study. Work with an expert partner to test the technology on your specific parts and production environment. Fail fast and learn quickly.

### Deploy & Scale:



Begin with a single line or application. Document the wins, build expertise, and then create a roadmap to scale the solution across other lines and facilities.

# Seeing the Bigger Picture



## Protect Your Brand:

Eliminate defects before they reach the patient.



## Ensure Compliance:

Automate UDI and traceability to meet global regulations.



## Drive Efficiency:

Reduce waste, lower inspection costs, and unlock new production data.



## The Technology is Ready:

With modern tools, deploying advanced vision is more accessible than ever.



# Let's discuss how AI vision can bring clarity to your operations.



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