Antimicrobial and detectable material considerations in contamination-sensitive environments

ABB Safety Series - Installation Products Division
Food & Beverage / Pharmaceutical /
Health and Hygiene / Personal Care

Helping reduce contamination risk in production environments

Insights on electrification and safety in Food & Beverage processing / Pharmaceutical / Health and Hygiene / Personal care

Antimicrobial and detectable material considerations in contamination-sensitive environments.

From food and medication to deodorant and toothpaste, we expect the products that touch our lives to be safe to consume and use. Helping prevent contamination in production environments and healthcare settings is critical to reducing risk and waste.

Every touchpoint across the food and beverage, pharmaceutical, health and hygiene, and personal care manufacturing spectrum is held to high standards of safety. Maintenance, monitoring and sanitation schedules overlay the entire operations, while assuring maximum uptime. Downtime in production environments can cost thousands of dollars per line per hour, as well as result in significant waste. From personnel and practices to processing and packaging, it's important to implement safety and hygiene controls at every stage.

Over decades in hygiene-critical environments, we've found most recalls and outages are preventable and contamination risk can be reduced with the right materials. Whether prompted by a recall or risk, identified through a site assessment, or integrated into planning, there are key areas we consistently find partners need to assess or address.

Microbiological contamination

Unauthorized substances or ingredients

Labeling issue

Minimizing contamination risk

Following concerns over adverse events and recalls associated with contaminated products, the US Food and Drug Administration (FDA) issued draft guidance[1] in September 2021 to help manufacturers control microbiological contamination of their non-sterile drugs (NSDs).

The draft addresses product development considerations, risk assessments, and good manufacturing practice (GMP) requirements for establishing "microbiological control" in an NSD manufacturing operation. The US Food and Drug Administration (FDA) reported it received 197 adverse event reports from microbiological or fungal contamination of non-sterile products between 2014 and 2017.

The FDA considers these events to be underreported and the actual number may be "significantly higher." During the same period, 50 recalls were associated with contaminated NSDs. Across these recalls, a "wide range" of objectionable organisms were found in aqueous and non-aqueous NSDs.[2]

1. https://www.fda.gov/media/152527/download
2. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/microbiological-quality-considerations-non-sterile-drug-manufacturing

Manufacturing considerations for products we eat, drink and that touch our lives.

Contamination-sensitive products and applications include:

Food & Beverage processing | **Pharmaceutical**

Meat / Aquaculture | **Dairy** | **Beverage** | **Agriculture / Ingredients** | **Infant food and formula** | **Pet food and treats** | **Dietary supplements and nutraceuticals** | **Pharmaceutical and vaccine production** | **Chemical compound manufacturing**

1 Environment

Whether targeting specific areas or the entire facility, applications in certain environments and contact zones require protection and plans that comply with electrical and sanitation standards. Industry requirements and standards such as NSF certification, provide third-party accreditation to help protect food, water and consumer products, as well as the environment. It is essential to use solutions that incorporate antimicrobial, detectable and hygenic designs across certain production environments.

Contamination-sensitive environments span the following:

- Food and beverage processing
- Food preparation and food service
- Health and Hygiene
- Schools and daycare, healthcare, hospital and senior facilities
- Health, wellness and protection items - hospital gowns and uniforms, clothing and wipes, surgical covers, masks, caps, and hospital bed products
- Pharmaceutical production
- Medical device manufacturing
- Chemical and compounds manufacturing
- Cosmetics manufacturing
- Dietary supplements and nutraceuticals
- Other contamination-sensitive industries such as personal care and other types of consumer products
- Clean rooms and Environmental rooms

A huge challenge is properly sanitizing behind or between equipment and processing areas. Depending on the type of processing, personnel can also pose a significant threat.

Health and hygiene | **Personal care** | **Packaging**

- Heath, wellness and protection - masks and wipes
- Medical device manufacturing
- Cosmetics manufacturing
- Soap, deodorant and toothpaste
- Children's and consumer products
- Packing and palletizing

2 Applications

Fasteners are found at every stage of processing and handling throughout facilities, connecting everything from conveyer belts to system wiring. Ty-Rap® cable ties are used for cable and wire management in applications including:

- Cable bundling or looping
- Suspending or elevating cords, equipment or wires
- Separating cables, conduit, equipment, pipes and wires
- Grouping cables or wires
- Securing hoses and tubing
- Patient monitoring equipment
- Portable or stable diagnostic and imaging systems
- Cameras for security, positioning and foot traffic monitoring
- Evaluation tables and treatment devices
- Temporary or semi-permanent lighting
- Safe positioning of electrical wiring and portable generators or heaters
- Ty-Rap® TyGenic™ antimicrobial* detectable cable ties are designed for use in indoor applications with operating temperatures up to 85°C (185°F)

The ABB team continually works with food and beverage, pharmaceutical and other partners to help match the correct solution to the application to assure products meet required ratings, standards and guidelines.

*** Note:** Ty-Rap® TyGenic™ antimicrobial detectable cable ties provide no antimicrobial inhibitory activity beyond protection of the cable ties themselves. They do not provide protection against specific pathogenic organisms, nor do they prevent growth of bacteria on adjacent or nearby surfaces. The antimicrobial efficacy of the material is designed to last for the life of the cable tie under normal use conditions.

Ty-Rap® TyGenic™ antimicrobial* detectable cable ties
are the industry's first two-piece cable tie that is both antimicrobial and detectable for use in food and beverage processing and other contamination-sensitive environments.

3 Detectability

Detection is key to prevention.
From raw ingredients and liquids to cutting and packaging, all manufacturers must have at least one type of detection equipment such as metal or x-ray technology.

Many producers use a combination of detection methods including:

- **Visual systems** such as cameras, monitoring and physical quality checks detect surface irregularities and volume changes. The deep blue color of Ty-Rap® TyGenic™ antimicrobial-treated detectable cable ties help ensure easy visual detection.
- **Metal detectors** and magnets. Ty-Rap TyGenic antimicrobial detectable cable ties are tested and verified to meet or exceed the detection of a 1.5 mm ferrous sphere, making them detectable by nearly every metal detector in service today.
- **X-ray technology** is increasingly used to identify glass, metal, porcelain, and bone fragments. Depending on product density, Ty-Rap TyGenic antimicrobial detectable cable ties display a differential of between 200 and 2000 on the x-ray gray scale.

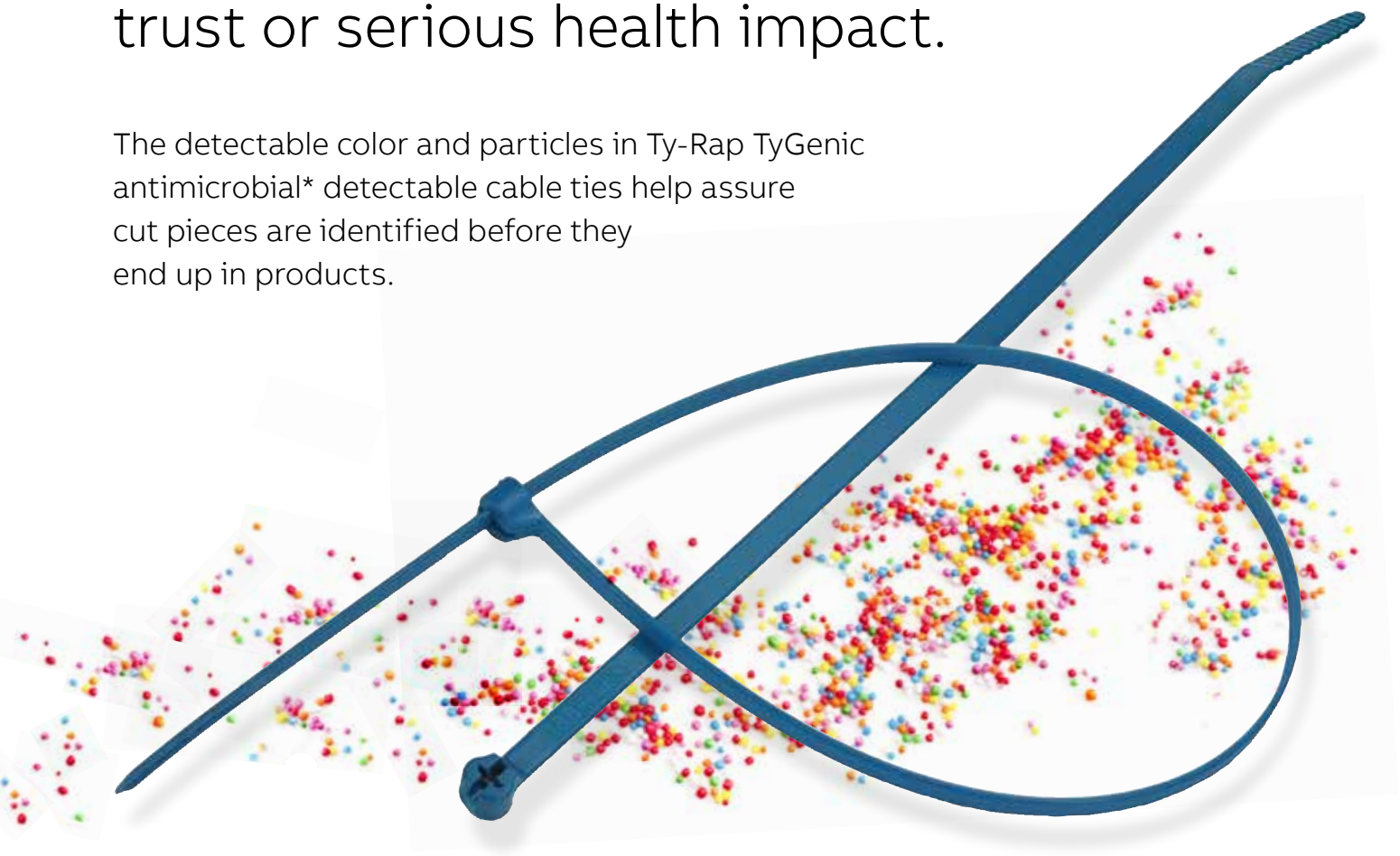
ABB introduced detectable Ty-Rap® cable ties in 2006 in a distinctive blue color for easy visual detection. Building on a long history of innovation, Ty-Rap TyGenic cable ties now offer three-way detectability and also help resist the growth of microorganisms.

The range of safe and smart Ty-Rap® cable tie solutions includes heat-reactive cable ties that change color to warn of potentially dangerous high temperatures and cable ties that have buoyancy for easy visual detection in batters and liquids.

The detectable color and particles in Ty-Rap TyGenic antimicrobial detectable cable ties help assure cut pieces are identified before they end up in products.

Contamination can be costly, resulting in downtime, waste, loss of customer trust or serious health impact.

The detectable color and particles in Ty-Rap TyGenic antimicrobial* detectable cable ties help assure cut pieces are identified before they end up in products.



4 Flexibility

In complex and constantly changing production environments, solutions that help serve multiple purposes are vital.
As advances in automation, technology and control capabilities are integrated into healthcare and production environments, flexible designs that allow for reconfigurations within an area or existing facility footprint are invaluable.
It's common for facilities and manufacturers to frequently modify equipment or change a process - sometimes every few months.

In this era of continuous operations, uptime and on-time delivery, manufacturing and medical facilities are seeking products that provide flexibility in adjusting to supply changes, demand surges, operational schedules and facility reconfigurations. Temporary or permanent cable and wire management solutions can make it easier, safer and more cost-effective to organize and update equipment, methods and spaces.

ABB's Ty-Rap® TyGenic™ cable ties help reduce risk, complement cleaning protocols and enhance safety for hygiene-critical locations.

Notches and grooves make an attractive home for microorganisms to collect and reproduce.

Tested to be over 99% effective at inhibiting microbial growth,
ABB's Ty-Rap TyGenic antimicrobial* detectable cable ties help protect against a broad spectrum of microorganisms such as bacteria, viruses, protozoans and fungi like mold and mildew.

5 Materials and methods

Materials matter and can significantly affect speed and ease of cleaning, performance and lifespan of electrical installations.
Title 21 Code of Federal Regulations regulates food contact materials and the conditions for their safe use[3]. Material selection considerations include:

- **Hygienic properties** such as antimicrobial and bacteria-resistant materials and surfaces that inhibit the growth of bacteria, fungi and mold.
- Ability to connect and fasten cables and wires to **allow for 360° access** and cleaning. The FDA's Food Safety Modernization Act requires everything attached to the walls inside food processing areas to be offset.
- **Testing for reliability** and meeting rating, maintenance and inspection requirements for its intended use.

[3] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=117.3

Electrical installations are designed and tested to meet the regulations and requirements for the environment including: IP, which is a global certification and test; UL (Underwriters Laboratory) third-party testing; NEMA ratings; FDA-compliant materials; NSF International for third-party accreditation; and IP69, if applicable. There are several different regulatory and governing bodies that provide input increasing safety.

Ty-Rap TyGenic antimicrobial* detectable cable ties are molded from an FDA-compliant, silver-free, nylon resin blend, containing an EPA-registered antimicrobial additive to help inhibit the growth of surface bacteria, fungi and mold. ABB's proprietary material is proven to be over 99% effective in eliminating common surface microbes in independent laboratory tests in accordance with ISO22196.

Designed for facilities where bacteria reduction and detectability are critical, ABB's Ty-Rap TyGenic cable ties help deliver compliance, quality and safety including:

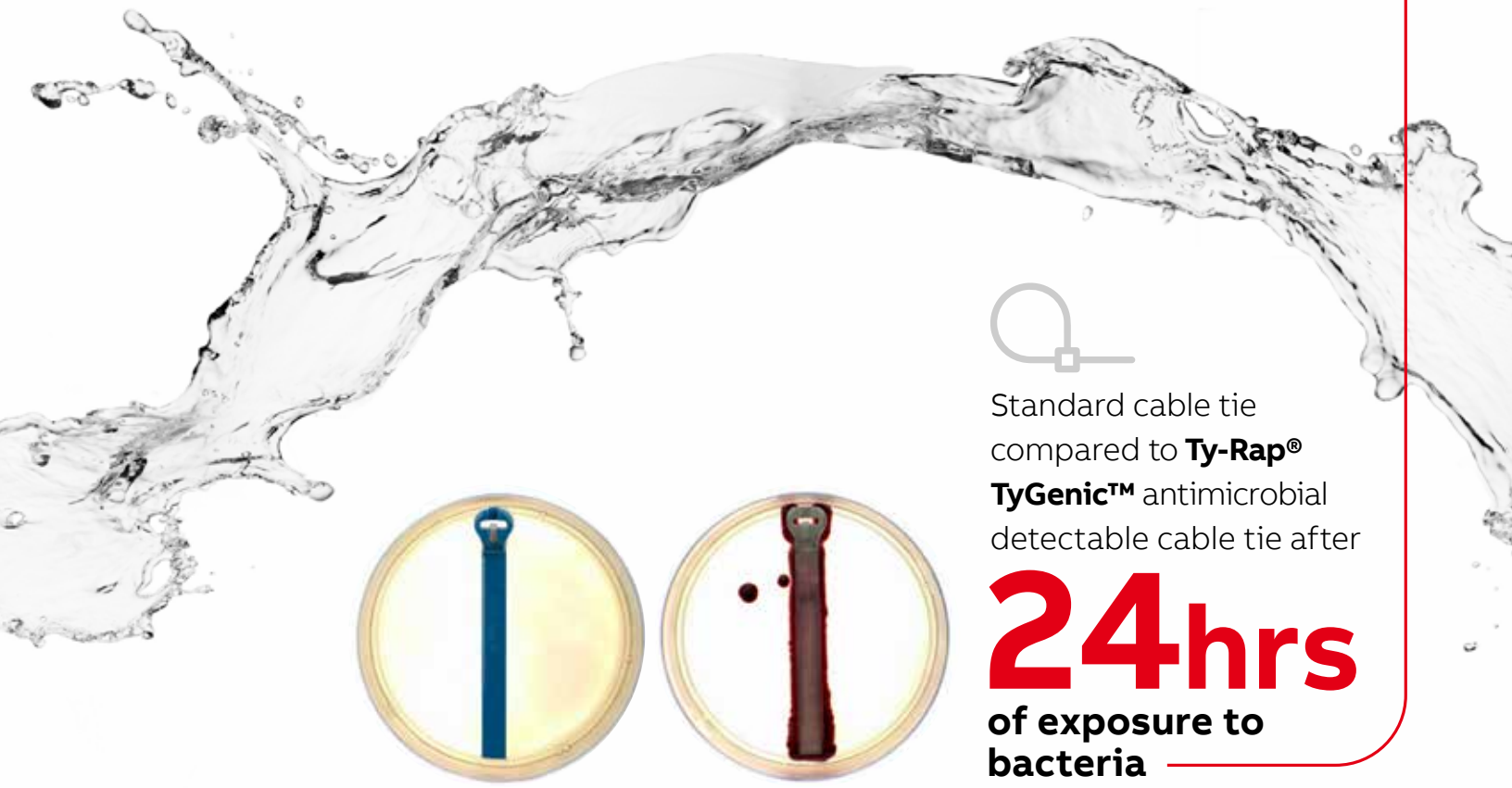
- **The industry's first two-piece cable tie** that inhibits microbial growth while also delivering X-ray, metal and visual detectability
- **Provides a surface** on which microbes cannot adhere and replicate
- Made from an FDA and EU **food contact-approved**, halogen-free nylon 6.6 (polyamide) resin blend
- UL **recognized** and RoHS **compliant**
- **Deep blue color for easy visual detection** – distinguishable from the lighter blue color of standard Ty-Rap® detectable cable ties
- **Offers the peformance** of standard Ty-Rap® cable ties, including "The Grip of Steel®" stainless steel locking device
- **Designed for use in indoor** applications with operating temperatures up to 85°C (185°F)
- Available in **four sizes**

* Patent pending

Hygienic - clean, sanitary, and contributes to health and disease prevention.

Antimicrobial - kills or slows the spread of microorganisms.

Bacteria-resistant - inhibits growth of bacteria, fungi and mold.



Standard cable tie compared to **Ty-Rap® TyGenic™** antimicrobial detectable cable tie after

24hrs

of exposure to bacteria

Safety comes down to materials, ratings and design features that make it easier to eliminate spots for bacteria and contaminates to hide.

No home for microorganisms
By design, a cable tie has notches that make an attractive home for microorganisms to collect and reproduce. ABB offers innovative solutions to help create cleaner, safer environments.

Detectable
The detectable particles and distinctive deep blue color of Ty-Rap TyGenic antimicrobial detectable cable ties help ensure fragments don't end up in the product.

6 Safety and prevention

Contamination often occurs due to mishandling along the production chain. Pre-emptive planning and identifying a material or process at any point in the manufacturing cycle that pose a contamination, recall or safety risk can help save lives.

Innovation and higher standards of safety and sustainability are being incorporated into nearly every aspect of production, helping prevent contamination, reduce waste and create cleaner environments. Despite proactive steps, the accelerated pace of change and drive to add new technology across everything from tools to transportation can result in implementation of quick or low-quality solutions.

In addition to the design and contamination resistance in creases, crevices and threads, consider materials that are safe to use in areas exposed to condensation such as inside an electrical system where corrosion can produce bacteria and pose risk.

Safeguarding against *secret ingredients*
Ensuring all electrical elements, from conduit and cable to fittings and fasteners, work in concert to enable the highest levels of safety and productivity is how ABB is helping protect hygiene-critical areas. We work with customers to look across their facilities and leverage ABB expertise across the entire processing spectrum, including raw materials, production, packing and transport.

Proven
Ty-Rap® TyGenic™ cable ties are tested to be more than 99% effective in preventing microbes from forming on its surface.

Ty-Rap® cables ties are tested and trusted in a wide range of applications on earth and in space.

Acknowledgments

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About ABB Installation Products

ABB Installation Products Division, formerly Thomas & Betts, is a global leader in the design, manufacture and marketing of products used to manage the connection, protection and distribution of electrical power in industrial, construction and utility applications. With more than 200,000 products under more than 38 premium brand names, ABB Installation Products solutions can be found wherever electricity is used.

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