



**BIOTRONIK**

excellence for life



# **BIOTRONIK, Inc.**

Code of Business Conduct

## A Message from the President of BIOTRONIK, Inc.



It has been a long-standing policy of BIOTRONIK to conduct our business with the highest standards of moral and ethical behavior. BIOTRONIK's global reputation for legal and ethical behavior is one of our most important assets, of which we can be proud.

The BIOTRONIK Code of Business Conduct is intended to inform employees and representatives of their legal and ethical obligations. Each of us is responsible to ensure understanding and compliance with "The Code". Compliance with The Code is not optional, it is mandatory for employees as well as anyone who represents BIOTRONIK including contractors and independent sales representatives.

The Code of Business Conduct helps define our values and should be used as a reference to help you make the right decisions and resolve ethical issues you may encounter. It has been designed to be a useful resource and I encourage you to refer to it often.

In addition to complying with The Code as individuals, we all share a responsibility for reporting and addressing violations of The Code. The Code prohibits retaliation against anyone who raises a concern, and I am personally committed to fostering an environment that encourages people to raise concerns. If you see a violation of The Code, you should tell your manager, Compliance, or alert me directly. We also have a Compliance hotline, which allows you to submit complaints anonymously.

We can maintain BIOTRONIK's commitment to quality products and standards only if we adhere to the business conduct standards.

Ryan Walters

President

BIOTRONIK, Inc.

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# Introduction





# BIOTRONIK

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## Our Company

In 1963, two students embarked on a mission to perfectly match technology with the human body. That remains our company's driving mission to this day. Dr. Max Schaldach and Otto Franke developed the first German implantable pacemaker, beginning the BIOTRONIK commitment to advance health and well-being for all people.

In 1979, BIOTRONIK expanded to the United States and other global markets.

BIOTRONIK's vision is for our technology to save, extend, or improve the life of **one person every second**.

# Core Values

## PASSION FOR INNOVATION

I challenge the status quo.

## DEDICATION TO QUALITY

I deliver the right quality, every time.

## EXPERTISE ACROSS ALL AREAS

I strive for excellence through continuous learning and development.

## COMMITMENT TO ETHICS AND COMPLIANCE

I do the right thing, all the time.

## A STRONG TEAM

I am a valuable contributor who helps our team win.



## Scope and Applicability of the Code

BIOTRONIK, Inc.'s Code of Business Conduct (the "Code") defines our ethical standards and governs the conduct of all BIOTRONIK personnel, including all employees, management, Board, as well as contractors or others who work with or on behalf of BIOTRONIK.

Each of us is responsible for understanding and complying with the Code. The Code should be used as a reference to help you make the right decisions and resolve ethical issues you may encounter.

In addition to the Code, our Company policies and Employee Handbook are further resources for you and act as key supplements to this Code.

If you are in doubt about the application of standards outlined in the Code, contact your manager or the Compliance Department.



# Legal and Regulatory Considerations

As a medical device company, we operate in a highly regulated space. BIOTRONIK does not tolerate bribery, corruption, kickbacks, or any other improper advantage in any of our business interactions involving healthcare professionals, government officials, or other third parties. We comply with all laws and regulations that apply to us including, but not limited to:

- Anti-Kickback Statute
- False Claims Act
- Open Payments Program
- Foreign Corrupt Practices Act
- Food, Drug, and Cosmetic Act
- Health Insurance Portability & Accountability Act
- Civil Monetary Penalty Laws
- Anti-Trust Laws



## Policies

BIOTRONIK is committed to maintaining high ethical standards and ensuring compliance with all relevant laws and regulations. To achieve this, we have established a comprehensive framework of policies and procedures that clearly outline our ethical standards, compliance requirements, and reporting mechanisms. Our policies are regularly reviewed and updated to ensure alignment with evolving requirements and industry best practices.

We ensure that our employees are familiar with our policies and guidelines, and we provide them with accessible resources and training to help them understand and adhere to these policies.

All BIOTRONIK policies are accessible through our Quality Management System.

# Responsibilities and Conduct



# Professional Conduct Standards

Acting in a professional, honest, and ethical manner is a top priority for BIOTRONIK. Employees or any third-party agencies acting on behalf of BIOTRONIK are expected to treat everyone with respect.

Every BIOTRONIK representative is expected to behave both within BIOTRONIK and towards third parties with integrity, mutual respect, holding open and fair dialogue, and honoring everyone's right to privacy and dignity.

BIOTRONIK supports equal opportunities for its employees and will not tolerate discrimination or harassment of any kind in the workplace. No one shall be discriminated against as a result of gender, age, disability, race, ethnic origin, religion or ideology, or sexual orientation. Discrimination, harassment, and insults will not be tolerated.



## Diversity, Equity, and Inclusion

BIOTRONIK is a place where all employees will be heard, uplifted and supported. We believe diversity, equity and inclusion is vital to creating and maintaining a successful workplace where people can thrive personally and professionally.

We believe that our commitment to include all races, genders, ages, religions, identities and experiences contributes to the success of our business and makes us a stronger company.

Unlocking the **power and potential of all** supports our common purpose to save and improve patient lives.

# Conflicts of Interest

A conflict of interest may occur when an individual's personal investments, interests, or associations interfere, or might interfere, with their responsibility to act in the best interests of BIOTRONIK.

Examples of potential conflicts of interest include, but are not limited to:

- Selling to a spouse or other family member (e.g., a sales representative selling to an implanting physician that is his or her spouse, child, parent, or sibling);
- Consulting for, or holding a second job with, a competitor, supplier, or customer;
- Holding a substantial financial interest in any competitor, supplier, or customer;
- Attempting to influence the selection of a contractor or supplier if that selection will result in personal financial gain (or financial gain of a spouse or family member);
- Starting a competing business or pursuing any commercial opportunity that would appear to interfere with the best interests of BIOTRONIK.

BIOTRONIK personnel must promptly disclose in writing actual or potential conflicts of interest to the Compliance department or Human Resources to determine whether a conflict of interest exists.



## Workplace Safety

BIOTRONIK is committed to providing a healthy and safe workplace environment for our employees. We strive to prevent workplace injuries, illnesses, and environmental issues by following all applicable environmental, health, and safety laws and regulations and complying with all BIOTRONIK health and safety policies and procedures within all our facilities and our customers' facilities.

Do not endanger yourself or others. You should immediately **report behavior** or activity that jeopardizes the safety of our workplace or the environment.

# Business Practices





# Product Quality and Promotion

BIOTRONIK has a long-standing reputation of high quality in product design and performance and believes that transparency on the quality and safety of our products is essential. We are dedicated to improving patients' lives through high-quality products, procedures, and services.

We follow the FDA's requirements on reporting product complaints, which is defined as any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. All complaints must be reported to the **Medical Device Reporting** department as soon as possible.

We only promote our products on-label, meaning we cannot promote a BIOTRONIK product for any use or indication outside those defined in the approved claims and/or indications for use in the United States.



# Customer Relations

We believe that every interaction with our customers, including healthcare professionals and institutions, is a valuable opportunity to demonstrate our commitment to honesty, integrity, service, and dedication. All information provided to our customers must be truthful, balanced, and approved through appropriate channels.

One relationship stands out as particularly important to us: the relationship between our company and our most vulnerable partners, **our patients**. We recognize that our life-saving products profoundly impact their lives, and we are committed to ensuring that the highest standards of care, ethics, and respect always characterize the interactions between BIOTRONIK and our patients.

We are proud of the many patients who benefit from our products, and we value the relationships we have with our customers and their trust in us.



## **Financial Integrity**

BIOTRONIK follows proper accounting and recordkeeping practices to ensure that we are accurately representing information that relates to our business, including financial records, timecards and statements.

All BIOTRONIK personnel are expected to follow document retention policies, and not allow unauthorized destruction or alteration of documents.

Fraud occurs when someone intentionally misrepresents, cheats or deceives to obtain a benefit or financial gain. Suspected fraud should be promptly reported.

## Fair Competition

BIOTRONIK is committed to open markets and fair competition. All BIOTRONIK personnel are expected to comply with anti-trust, and other applicable laws pertaining to fair competition. These laws generally prohibit the following behavior:

- Unfair trade practices, including bribery, misappropriation of proprietary information, deception, intimidation, or similar practices;
- Discussions with competitors pertaining to pricing, bids, discounts, promotions, profits, costs, terms or conditions of sale, warranties, or inventories;
- Discussions and agreements with competitors to allocate customers, or divide territories;
- Discussions and agreements with competitors to refrain from doing business with a particular company or to limit doing business with a particular company.



# Information and Communication



# Confidential Information

BIOTRONIK's confidential information must be protected from disclosure and only used as authorized.

Confidential information is information that is not publicly available and may include:

- Personal or employee information, such as private contact information, health history and government identification numbers
- Professional or management information, such as performance reviews and disciplinary actions
- Business information, such as business plans, models, financial data, customer and prospect lists, sales goals and price lists, marketing strategies, trade secrets, research and development projects

If confidential information is compromised in any way, report the incident to the IT Helpdesk immediately.

# Protecting Patient Information

Certain BIOTRONIK Personnel may encounter patient Protected Health Information (PHI) as part of their job. We treat PHI with the utmost care and have strict safeguards in place to protect against any unauthorized disclosure or use.

At a minimum, BIOTRONIK Personnel should always safeguard PHI by:

- Ensuring that there is no unauthorized disclosure or use of, and no unauthorized access to, patient PHI.
- Safeguarding passwords, ensuring the security of mobile devices, and using only encrypted company-managed mobile devices for the transmission of PHI.
- Never discussing, copying, or photographing PHI outside the context of patient care.
- Reporting any potential or suspected breach of PHI to Quality Systems or [dataprivacy.us@biotronik.com](mailto:dataprivacy.us@biotronik.com) immediately.



## Social Media

BIOTRONIK recognizes the benefits of social media platforms and the increasing importance of playing an active role on them, while also understanding that use of social media brings certain risks.

We need to be mindful of reputation and consider how statements made online may reflect on the company. All BIOTRONIK personnel are responsible for understanding careful communication, following company policies, and using good judgement, especially on social media where interactions are widely visible.

Refer to [BIOTRONIK's Communication Policy](#) for detailed information.



# Reporting Concerns



# Reporting Hotline

Employees and others working on behalf of the company should always feel comfortable when raising concerns about ethics and compliance issues. We take your concerns seriously, we investigate all reports thoroughly, and we will not tolerate retaliation against those who express their concerns.

We encourage employees to ask questions, obtain guidance, or report a concern directly to their manager, the Compliance department or through our reporting hotline (which can be done anonymously).

Available 24 hours a day, 7 days a week

**Online Portal:** [biotronik.ethicspoint.com](https://biotronik.ethicspoint.com)

**Mobile-Friendly:** [biotronikmobile.ethicspoint.com](https://biotronikmobile.ethicspoint.com)

**Call 1 (833) 208-6080**

# Enforcement and Discipline

BIOTRONIK has a **zero-tolerance** policy for major violations of the Code and other BIOTRONIK policies. Major violations include but are not limited to knowingly violating laws or regulations, fraudulent activities, retaliation, and falsifying documents.

BIOTRONIK enforces compliance with this Code through appropriate disciplinary mechanisms. Disciplinary procedures are weighted according to the nature of the violation committed and the employee's compliance history. Compliance-related disciplinary action may be documented in the employee's personnel record maintained by Human Resources.

Some matters prohibited by the Code may also violate state or federal laws, and could lead to individual criminal prosecution, significant fines, and/or imprisonment.

Any BIOTRONIK personnel who is, or because of their duties should have been, aware of a violation of law or regulation or BIOTRONIK policies and who fails to make a timely report, likewise is subject to disciplinary action, up to and including termination.

# A Closing Message from the Vice President, Compliance & Risk Management

Our actions and intentions define us as individuals and serve as the basis of our professional reputations. Our decision making, whether we are employees, contractors or independent representatives directly impact how our customers, patients and communities view us as

individuals, and BIOTRONIK as a whole. How we treat others, the manner in which we speak, our ability to navigate through business and ethical issues, and the passion and values we bring to our jobs every day, all determine our success and its sustainability.

We are all part of a company with a deep history of innovation, quality, and excellence, whose driving mission is improving and saving lives. We win together, and for better or worse, we lose together. If you don't know how to resolve a difficult situation, ask your manager, speak to your colleagues, or contact me or my department directly.

I am grateful for all you do for this amazing Company. We are in this together!

**Jason Spinazzola**

Vice President, Compliance & Risk Management  
BIOTRONIK, Inc.



# Resources

In addition to the Code, the following resources are available for use:

- [P1022: Interactions with U.S. HCPs Policy](#)
- [Compliance and Ethics Page on BIOTRONIK's Intranet](#)
- [Reporting Hotline](#)
- [AdvaMed Code of Ethics](#)
- [Employee Handbook](#)
- Quality Management System which houses all BIOTRONIK, Inc. policies and procedures including:
  - [P1002: Travel and Reimbursement Policy](#)
  - [P1008: Communications Policy](#)
  - [P1012: Conflicts of Interest Policy](#)
  - [SOP-036: Enforcement and Discipline](#)
  - [SOP-070: Exclusion Screening](#)
  - [SOP-035: Compliance Investigations](#)
  - [SOP-034: Procurement](#)
  - [SOP-021: Marketing Documents](#)
  - [SOP-007](#) and [SOP-046](#): Complaints, Returned Products, and Medical Device Reporting
  - [SOP-049: Compliance with HIPAA](#)