

# CORPORATE CODE OF CONDUCT

ORTHOFIX INTERNATIONAL N.V. & ITS SUBSIDIARIES ("ORTHOFIX")



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## Our Vision

Our vision is to be a highly respected orthopedic and spine company that delivers exceptional value to our patients, customers, team members, partners and shareholders.

## Our Mission

Our mission is to improve patients' lives by providing superior reconstructive and regenerative orthopedic and spine products to physicians worldwide.

## Scope

This Corporate Code of Conduct ("Code"), which explains our core values, is also designed to affirm and promote those values and the standards of ethical conduct described below. It applies to Orthofix and all its worldwide affiliates ("Orthofix" or the "Company"), and every person working for or on behalf of the Company, including as a director, officer, or employee. We also expect third parties representing the Company, such as an agent or distributor, to abide by this Code.

The Code covers a wide spectrum of topics and many basic principles regarding our business practices, but it cannot cover every issue that may arise. Our Company policies and procedures are a further resource for you and act as key supplements to this Code. Use good judgment and common sense in everything you do on behalf of the Company. Ask questions of your supervisor, the Compliance Office, or the Company's General Counsel if you are unsure about any aspect of this Code or its application in any situation.

### Your Responsibilities...

- ✓ **Read and review the Code of Conduct and related policies and procedures.**
- ✓ **Become familiar with all laws, regulations, policies and procedures that impact your duties at or for Orthofix.**
- ✓ **Ask questions if you are not sure what exactly it is that you are supposed to do.**
- ✓ **Use good common sense and sound judgment in the performance of your duties and responsibilities.**
- ✓ **Promptly report potential violations of any law, regulation, or the Code to your manager or the Compliance Hotline.**
- ✓ **Managers must ensure that their teams comply with laws, regulations, and policies, and must work to resolve ethical dilemmas.**

# Purpose

Excellence with integrity is the key to Orthofix's continued success in all our dealings with customers, patients, shareholders, employees, regulators and others with whom we do business. This Code of Conduct (the "Code") expresses the standards of integrity and business conduct expected of every employee, director, and officer of Orthofix as well as all contracted Orthofix associates. Compliance with this Code, other company policies and the laws and regulations applicable to our business are a priority for each of us in order to preserve our priceless reputation and ensure our future success.

The goals of Orthofix's Code and Corporate Compliance Program are to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- The full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the United States Securities and Exchange Commission and in other public communications made by Orthofix;
- Compliance with all applicable governmental laws, rules and regulations;
- The prompt internal reporting of violations of the Code; and
- Accountability for adherence to the Code.

# ACCURACY IN FILING CLAIMS

(Applies to U.S. Bone Growth Stimulation Businesses)

Accurate billing and submission of claims is a top priority for Orthofix. We are committed to developing and maintaining policies and procedures that:

- Ensure accurate billing and submission of claims for only those medically necessary products and services that are actually provided by eligible personnel; and
- Comply with all laws, regulations and guidelines.

If it is determined that an error was made in the preparation or submission of a bill or claim, it is Orthofix's policy to take appropriate corrective action. Corrective action may mean a number of different things, depending on the situation. For example, corrective action may include:

- resubmitting the claim;
- revising existing Orthofix policies and procedures, or associate training; and
- where appropriate, contacting government authorities.
- The Compliance Committee will determine the appropriate corrective action for the situation.

## **Your Responsibilities...**

- ✓ **Do not file a claim for services that were not provided or for services different than described on the claim forms.**
- ✓ **Do not file a claim you know to be misleading or false in any way.**
- ✓ **Contact the Compliance Office if you think a mistake has been made in a bill or claim.**
- ✓ **Initiate corrective actions, if and when an error in claim processing has been discovered.**
- ✓ **File claims only for services that were medically necessary.**
- ✓ **Provide all appropriate documentation of services furnished with all claims submitted.**
- ✓ **Check the bill to see if it is supported by the diagnosis or documentation.**
- ✓ **Ask questions if you are unsure about the accuracy of any claim for services.**
- ✓ **Report suspected violations of this policy.**

**"Unintentional mistakes have consequences"**

# ACCURATE FINANCIAL REPORTING

## ***Retention of Financial Records***

It is Orthofix's policy to maintain financial records in an accurate and complete manner. These records serve as the basis for managing the business and measuring and fulfilling our obligations to patients, employees, suppliers and shareholders. These records are also used for compliance with tax, regulatory and financial reporting requirements.

## ***Accounting Controls***

Accounting controls should be sufficient to provide reasonable assurance that:

- Financial contracts are carried out with management's approval.
- All transactions are recorded to help us prepare our financial statements and account for assets.
- Access to assets is permitted only with management's approval.
- Recorded assets are periodically compared with existing assets. Any differences should be reported to management.
- No undisclosed or unrecorded funds or assets have been established.

## ***Internal Controls***

It is Orthofix's policy to maintain books, records and accounts that accurately and fairly reflect all transactions, dispositions of assets and other events that are the subject of specific regulatory record keeping requirements, including generally accepted accounting principles and other applicable rules, regulations and criteria for preparing financial statements and for preparing periodic reports filed with the United States Securities and Exchange Commission (SEC). Under no circumstance may there be any unrecorded liability or fund of Orthofix, regardless of the purposes for which the liability or fund may have been intended, or any improper or inaccurate entry knowingly made on the books or records of Orthofix.

As noted in the Orthofix Records Retention Schedule, Standard Operating Procedure Number RF592007, no applicable documents will be destroyed during an investigation initiated by authorities.

## **Your Responsibilities...**

- ✓ **Follow all company accounting, reporting and control procedures.**
- ✓ **Never falsify, backdate, intentionally destroy or otherwise tamper with any records.**
- ✓ **Accurately and clearly represent the relevant facts and the true nature of transactions on all documents.**
- ✓ **Never approve any payment on behalf of Orthofix made with the intention, understanding or awareness that any part of the payment is to be used for any purpose other than that described by the documentation supporting the payment.**
- ✓ **Never misclassify accounts (e.g., expense versus capital) or improperly accelerate or defer expenses or revenues.**

# COMPLIANCE WITH LAWS

## ***Anti-Bribery and Anti-Corruption***

As a global company, Orthofix must comply with the anti-bribery and anti-corruption laws and regulations of every country in which it operates. Generally, these laws prohibit the payment of bribes and other illegal payments to Government Officials anywhere in the world. Moreover, as a company registered in the U.S. market, Orthofix is subject to the stringent requirements of the U.S. Foreign Corrupt Practices Act (“FCPA”), the anti-corruption statute most actively enforced against U.S.-registered companies operating globally. We are also, however, required to comply with all other relevant laws and regulations against bribery and corruption in the countries where we conduct business around the world, including, but not limited to, the U.K. Bribery Act (“UKBA”), and the anti-corruption laws of Germany, France, Italy, and Brazil.

Specifically, Orthofix prohibits its directors, officers, managers, and employees, and all third parties retained by the Company, from engaging in any corrupt activity and directly or indirectly offering, promising, providing, or authorizing anyone to provide money or anything of value to a Government Official (or any private individual or entity) for the purpose of obtaining or retaining any improper advantage.

The commitment of all Orthofix personnel to compliance with this important policy is key to the Company’s success and competitiveness in the international business environment in which we function. Details relating to the requirements that all Orthofix directors, officers, managers, employees, and third parties must adhere to with respect to anti-corruption are set forth in detail in the Company’s Global Anti-Corruption Policy. That Policy must be read in conjunction with this section of the Code.

Any questions relating to the high standards Orthofix maintains with respect to anti-bribery and anti-corruption compliance should be directed to the Compliance Office.

## ***Antitrust and Competition***

Our business is subject to U.S. antitrust laws and competition laws of the countries in which we operate. Our policy is to compete vigorously and ethically while complying with all antitrust and competition laws. Antitrust and competition laws are designed to protect consumers and competitors against unfair business practices and to promote and preserve competition. These laws, among other things, prohibit or restrict activities related to fixing, coordinating or controlling prices and allocating or dividing customers, territories or markets.

As a result, you should limit communication with competitors to only that which is necessary and you must not communicate with competitors concerning activities that could be deemed to restrict competition, fix or control pricing or otherwise coordinate market actions. Do not



make false, misleading, deceptive, or fraudulent statements regarding the Company's products and services or regarding the products and services of our competitors. Do not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation, or any other unfair practice.

### ***Insider Trading***

Insider trading means entering into a transaction to buy or sell securities, such as shares of stock, while in possession of material information that is not known to the public. Information is "material" if a reasonable investor would attach importance to the information in deciding whether to buy, sell or hold the securities or if the information could cause a change in its market price. Examples of information that is generally considered "material" include financial results and pending corporate transactions.

The trading of securities while in possession of material, nonpublic information is illegal and, if the trades are made in the Company's stock, it is a violation of Orthofix policy. Material, nonpublic information obtained concerning other companies, including our suppliers and customers, as a result of your employment with the Company, also may not be used by you under law to trade in such other company's securities. You are also prohibited from communicating (called "tipping") any such information to others who might trade on the basis of that information. If you have regular access to material, nonpublic information concerning the Company or another company, you need to take special care when planning your stock trades.

The laws against insider trading are complex. If you are uncertain about the constraints on your purchase or sale of Orthofix securities or the securities of any other company that you are familiar with by virtue of your relationship with the Company, you should consult with the Company's General Counsel before making such purchase or sale. Note that certain employees are subject to "blackout" periods where they are strictly prohibited from trading. These generally coincide with the announcement of the Company's quarterly financial reporting. Details relating to the requirements that all Orthofix directors, officers, managers, employees, and third parties must adhere to with respect to insider trading are set forth in detail in the Company's Insider Trading Policy. That Policy must be read in conjunction with this section of the Code.

### ***Data Privacy and Data Protection***

The collection, use, storage, and international transfer of personally identifiable information about individuals is increasingly subject to regulations in the U.S. and other countries. We are committed to complying with all applicable data protection and privacy laws in the countries where we operate. You should carefully protect all personal information you acquire or have access to by virtue of your employment with Orthofix. This includes personal information about Company employees, customers, vendors, suppliers, partners and other third parties with whom the Company does business.

***Environmental Protection***

Orthofix strives to maintain a clean and healthy environment, and to this end, we are committed to complying with all federal, state and local environmental protection laws.

To protect the safety of our workforce, all associates must safely manage hazardous materials and waste from point of entry to the point of final disposal. All hazardous material and other waste products must be identified, handled, labeled and disposed of according to Orthofix policy.

***Political Contributions***

Employees may not contribute or donate Orthofix funds, products, services or other resources to any political cause, party or candidate. Employees and contracted business associates may make voluntary personal contributions to lawful political causes, parties or candidates as long as they are not represented as coming from Orthofix.

***Trade Restrictions and Export Controls***

The U.S. and other countries have laws imposing restrictions on exports and other dealings with certain countries, entities and individuals. These restrictions apply to:

- Exports to prohibited countries;
- Investments in and other dealings with sanctioned countries or with designated individuals; and
- Export of articles or services designed or adaptable for military application.

An “export” occurs when a product, service, technology, or piece of information is shipped to a person in another country. An export can also occur when technology, technical information or software is provided in any way, including verbally, to a foreign citizen located in either the U.S. or a third country.

**Your Responsibilities...**

- ✓ **Dispose of regulated medical waste or other waste according to Orthofix policies and procedures.**
- ✓ **Report any spills, leaks or unsafe storage of hazardous materials or waste.**
- ✓ **Wear the proper protective equipment and clothing designed to safely handle materials.**
- ✓ **Caution anyone else handling hazardous materials improperly.**

**Your Responsibilities...**

- ✓ **Never contribute or donate Orthofix resources to any political cause, party or candidate.**

Before engaging in exporting activity, you must verify the eligibility of both the location of delivery and the recipient. The Company must also obtain all applicable licenses and permits, and pay required duties. The list of prohibited countries and restrictions is always subject to change. Therefore, if you are involved in international trade activities you should contact the Company's General Counsel whenever you are unsure as to what is permissible and how to appropriately clear products for export.

### ***Anti-Money Laundering***

Orthofix is committed to complying with all applicable anti-money laundering laws, rules and regulations of the U.S., the U.K., Germany, France, Italy, Brazil, and other countries where Orthofix operates.

Anti-money laundering laws and implementing regulations generally prohibit companies from engaging in any financial transactions involving funds derived from illegal activities. If you believe that Orthofix or another party to a business transaction is engaged in any illegal activity or is using or transferring proceeds derived from an illegal activity, immediately contact the Legal Division or Compliance Office to notify them so they can consider the appropriate response.

### ***Anti-Kickback Statute***

The Federal Anti-Kickback statute generally prohibits offering or paying (or soliciting or receiving) cash or other benefits to induce the purchase, order, or recommendation of products eligible for payment by a federal health care program.

The statute is designed to capture fraudulent or abusive practices that could encourage overutilization or otherwise increase federal health care program costs, or bias treatment decisions by health care providers.

Note that even normal business practices (discounts, for example) can sometimes violate the law if they fall outside of the designated "safe harbors" contained in the statute – particularly if they lack appropriate safeguards.

To ensure Orthofix's compliance with the anti-kickback statute, we must carefully evaluate and properly structure any arrangements with parties in a position to prescribe, purchase or recommend government-reimbursed products (for example, physicians, hospitals, nursing facilities, HMOs, PBMs, GPOs, or pharmacies), and must always avoid any arrangements that could inappropriately influence treatment or purchasing decisions.

# CONFLICTS OF INTEREST

It is every employee's obligation to ensure that he or she remains free of conflicts of interest in the performance of his or her responsibilities at Orthofix. A conflict of interest may occur if your outside activities or personal interests influence (or appear to influence) your ability to make objective decisions in the course of your job responsibilities. A conflict of interest may also exist if the demands of any outside activities hinder or distract you from the performance of your job or cause you to use Orthofix resources for purposes that are not business-related.

In dealing with current or potential customers, suppliers, contractors, and competitors, each employee and contracted business associate must act in the best interests of Orthofix to the exclusion of personal advantage.

- No employee or immediate family member of an employee or contracted business associate may have a significant financial interest in, or obligation to, any outside enterprise which does or seeks to do business with Orthofix or that is an actual or potential competitor of Orthofix, without prior approval of the Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof.
- No employee or contracted business associate may conduct a significant amount of business on Orthofix's behalf with an outside enterprise which does or seeks to do business with Orthofix if an immediate family member of the employee is a principal, officer or employee of such enterprise, without prior approval of the Orthofix Corporate Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof.
- No employee or immediate family member of an employee may serve as a director, officer or in any other management or consulting capacity of any actual or potential competitor of Orthofix.

## Your Responsibilities...

- ✓ **Promptly report any financial, business or family relationship with an Orthofix competitor, customer or supplier to your manager, the compliance committee or the Orthofix Compliance Hotline.**
- ✓ **Obtain prior approval from the Orthofix Corporate Compliance Committee before making a financial investment in any competitor, customer or supplier of Orthofix.**
- ✓ **Obtain prior approval from the Orthofix Corporate Compliance Committee before accepting any consulting or other business relationship with an Orthofix competitor, customer or supplier while still employed with Orthofix.**

- No employee or contracted business associate may use any company property or information or his or her position at Orthofix for his or her personal gain.
- No employee may engage in business activities that are directly competitive with those in which Orthofix is engaged.
- No employee may divert a business opportunity from Orthofix for his or her own benefit.
- No employee or immediate family member of an employee may receive any loan or advance from Orthofix, except in limited circumstances.

Each employee and contracted business associate must promptly and fully disclose in writing to the Orthofix Corporate Compliance Committee any situation that may involve a conflict of interest. Failure to disclose any actual or perceived conflict of interest is a violation of the Code. In addition, the Audit Committee of the Board of Directors will review and approve all related-party transactions, as required by the U.S. SEC, the Nasdaq Stock Market or any other regulatory body to which Orthofix is subject.

# COMPANY ASSETS

Proper protection and use of Orthofix assets and assets entrusted to it by others, including proprietary information, is a fundamental responsibility of each Orthofix employee. Employees must comply with security programs to safeguard such assets against unauthorized use or removal, as well as against loss by criminal act or breach of trust.

## ***Proper Use of Orthofix Assets***

The removal from Orthofix's facilities of Orthofix property is prohibited, unless authorized by Orthofix. This applies to furnishings, equipment, and supplies, as well as property created or obtained by Orthofix for its exclusive use – such as client lists, files, personnel information, reference materials and reports, computer software, data processing programs and databases. Employees may not remove originals or copies of these materials from Orthofix's premises or use them for purposes other than Orthofix's business without prior written authorization from the Orthofix Corporate Compliance Committee. Orthofix's products and services are its property -- contributions made by any associate to their development and implementation remains Orthofix's property even if the individual's employment or directorship terminates.

## ***Proprietary Information***

Information, ideas and intellectual property rights are valuable assets of Orthofix. Information obtained, developed, or produced by Orthofix and its employees and information supplied by others for the benefit of Orthofix are confidential. Information pertaining to Orthofix's competitive position or business strategies, payment and reimbursement information is confidential. This information should not be shared with anyone outside of Orthofix and should be shared only with employees who have a legitimate need to know such information in order to perform their job responsibilities and who have agreed to maintain the confidentiality of the information.

## ***Confidential Information***

Orthofix provides its employees with confidential information relating to Orthofix and its business with the understanding that such information is to be held in confidence and not

### **Your Responsibilities...**

- ✓ **Do not discuss or provide Orthofix's confidential business information to anyone outside the Company without approval by the Compliance Committee.**
- ✓ **Never remove Orthofix property without prior approval from the Compliance Committee.**
- ✓ **Guard access to employee and confidential business information.**
- ✓ **Only share information with fellow employees who have a legitimate need to know the information.**

communicated to anyone who is not authorized to see it, except as may be required by law. The types of information that each employee must safeguard include (but are not limited to) Orthofix's plans and business strategy, unannounced products and/or contracts, sales data, significant projects, customer and supplier lists, patents, patent applications, trade secrets, manufacturing techniques and sensitive financial information, whether in electronic or conventional format. These are costly, valuable resources developed for the exclusive benefit of Orthofix. No employee may disclose Orthofix's confidential information to an unauthorized third party or use Orthofix's confidential information for his or her own personal benefit.

## **PATIENT PRIVACY**

Orthofix's business requires that we gather a great deal of personal information about individuals to whom we provide products and services. Therefore, we must carefully avoid any unwarranted invasion of our patients' privacy rights. Every Orthofix employee and contracted business associate must protect information concerning the treatment, payment, care and condition of all patients and may not disclose confidential patient information to any unauthorized person. Employees and contracted business associates must adhere to all Orthofix policies and procedures regarding compliance with the Privacy Rule and Security Standards promulgated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Employees and contracted business associates must avoid patient care conversations and discussions in areas where visitors and the public may overhear them. Written and computerized medical patient information can never be removed from Orthofix property without Orthofix Corporate Compliance Committee approval.

## **WORKPLACE CONDUCT**

Orthofix's goal is to offer high-quality products and services while providing a workplace that promotes respect, fairness, and open communications. The principles outlined below help create a workplace that encourages employees to optimize their contributions to Orthofix's mission.

### ***Equal Employment Opportunity***

It is Orthofix's policy to provide equal employment opportunity to all employees and job applicants. Orthofix prohibits discrimination or harassment against any person because of his or her race, color, sex, age, disability, religion, sexual orientation, ancestry, marital status or national origin.

## ***Harassment***

Orthofix is committed to providing a work environment that promotes respect and dignity for every employee. Harassment, in any form, will not be tolerated.

## ***Alcohol and Substance Abuse***

The possession, consumption, sale or purchase of alcohol or illegal drugs on Orthofix property is prohibited. Orthofix also prohibits the use of alcohol or illegal drugs by employees either directly before or during the workday. The Compliance Committee may occasionally approve limited alcohol availability for specific Orthofix functions.

## ***Occupational Safety and Health***

We are committed to providing a safe and healthy work environment for employees. All employees are expected to comply with the occupational safety & health laws that are applicable to their job, as well as the facility policies. Orthofix's goal is to be "Accident Free."

## ***Employee Confidentiality***

Every employee has an obligation to respect and protect the confidentiality of records regarding the personal information of other employees. Information such as employees' names, addresses, salaries, benefits, performance evaluations, credit information, medical information and employment histories is also considered confidential and must not be discussed with anyone, including any Orthofix employees, except as required to perform one's job.

### **Your Responsibilities...**

- ✓ **Never treat another employee differently because of his or her race, color, age, sex, religion, sexual orientation, disability, ancestry, marital status or national origin.**
- ✓ **Never make any sexual advances toward another employee.**
- ✓ **Do not make or tolerate any comments or jokes of a sexual or discriminatory nature.**
- ✓ **Never drink alcohol before or during your working hours or have possession of or use illegal drugs.**
- ✓ **Help to maintain a safe and healthy working environment.**



# GIFTS AND ENTERTAINMENT

Employees must not allow themselves to be influenced by customers or third parties in a manner detrimental to Orthofix. Conversely, we must not offer customers or third parties any gifts or other items of value as a regular practice, particularly regarding public officials.

However, Orthofix recognizes that exchanging gifts and gratuities can be part of building business relationships when done in accordance with the law and our Company policies. The use of Orthofix funds or assets for gifts, gratuities or other favors to develop or enhance business relationships is subject to a standard of reasonableness. Any such gifts, gratuities or favors must never be in cash, should be generally infrequent and must follow all applicable Orthofix guidelines.

You must not accept, or permit any member of your immediate family to accept, any gifts, gratuities or other favors from any customer, third party or other person doing or seeking to do business with Orthofix, other than items of nominal value and received for a legitimate business purpose. Any gifts that are not of nominal value should be returned immediately and reported to your supervisor or the Compliance Office.

Use common sense, reasonableness, and moderation when you engage in business entertainment on behalf of Orthofix. Any business entertainment provided to or accepted from anyone doing business with the Company must be limited to entertainment that is infrequent, modest, and intended to serve legitimate business goals. Similarly, it is against Orthofix policy to give payments, gifts or gratuities to the patients to whom we provide products and services. In this regard, regarding the U.S. Bone Growth Stimulation Business, unless there is demonstrated financial hardship, it is Orthofix's policy to bill for all applicable co-insurance and deductible amounts and to make reasonable efforts to collect such amounts from the beneficiary or from any other person or entity legally responsible for the beneficiary's medical bill (*e.g.*, local welfare agency, guardian, supplemental insurance).

## **Responsibilities...**

- ✓ **Recognize that exchanging gifts or providing entertainment can be part of regular business activity.**
- ✓ **However, Orthofix funds should be used infrequently for gifts or entertainment and only where there is a legitimate business purpose.**
- ✓ **Use common sense, reasonableness, and moderation with respect to offering or accepting gifts or entertainment, particularly with respect to Government Officials.**

# GIFTS TO PATIENTS OR REFERRAL SOURCES

## ***Avoiding the Appearance of Impropriety***

Orthofix does not want to give or receive business through the improper use of business courtesies, relationships, or gifts. All business relationships will be entered into on the basis of factors such as price, quality, performance, service, delivery and reputation.

Accordingly, Orthofix employees and contracted business associates may not provide any entertainment or gifts to a physician, hospital staffer, or other person in a position to refer business to Orthofix. Provision of items could be viewed as being made in exchange for favorable treatment or advantage. An employee or contracted business associate may provide modest refreshment, (meals, drinks) in connection with educational programs or business meetings only if such courtesies are unsolicited, infrequently provided and modest in amount and allowable by law.

Similarly, it is against Orthofix policy to give payments, gifts or gratuities to the patients to whom we provide products and services. In this regard, regarding the U.S. Bone Growth Stimulation Business, unless there is demonstrated financial hardship, it is Orthofix's policy to bill for all applicable co-insurance and deductible amounts and to make reasonable efforts to collect such amounts from the beneficiary or from any other person or entity legally responsible for the beneficiary's medical bill (*e.g.*, local welfare agency, guardian, supplemental insurance).

## **Responsibilities...**

- ✓ **Do not give any business courtesy that could be viewed as an attempt to gain favorable treatment or advantage.**
- ✓ **Do not provide reimbursement for lodging or travel expenses or free lodging or travel without the express written approval of the Compliance Committee.**
- ✓ **Make good faith attempts to collect patient coinsurance amounts owed to Orthofix.**
- ✓ **Do not waive a patient's financial obligation unless the patient has demonstrated a financial inability to pay.**

# EXTERNAL COMMUNICATIONS

## ***Marketing and Advertising Activities***

Orthofix advertising should be truthful, fair, accurate, complete, in alignment with regulatory approved indications and supportive of Orthofix's mission. In conducting marketing and advertising activities, Orthofix employees and contracted business associates may offer factual information or documented evidence to the general public. Marketing and advertising should not distort the truth or make false claims intended to attack or disparage our competitors. All Orthofix marketing activities require approval of the Marketing Department prior to initiation, and if they involve giving anything of value to a patient or to a potential source of patient referrals, advance approval from the Orthofix Corporate Compliance Committee.

## ***Contract Negotiation***

We are committed to providing services that meet all contract requirements and Orthofix's high quality standards. We also strive to be fair and consistent in the negotiation and formation of our contracts. Therefore, all information and data provided by associates should be current, complete and accurate. Employees should never withhold or falsify any information sought from another employee in connection with the negotiation or formation of a contract.

## ***Public Statements***

Since corporations are subject to increasing public scrutiny, it is important that any public statement that might attributed to Orthofix be carefully considered and that personal views be kept separate from company views. Employees may not speak publicly for Orthofix unless specifically authorized by senior management. Employees may not associate Orthofix with, or imply a company endorsement of, any personal political activity unless authorized to do so by Orthofix. Employees may not use company stationery or titles in communications involving non-Orthofix business (*e.g.*, a personal letter to the editor). Employees may be able to obtain an exception to this policy for an occasional use of stationery for routine correspondence in connection with appropriate outside civic, public service or charitable activities, when approved by the Compliance Committee.

## **Your Responsibilities...**

- ✓ **Accurately reflect Orthofix's capability and intent in all advertising and marketing materials and activities.**
- ✓ **Obtain approval from the Marketing Department or Compliance Office before conducting a marketing or advertising activity that would have Compliance Program implications.**
- ✓ **Adhere to the terms and conditions of contracts with our customers and suppliers.**
- ✓ **Provide complete and accurate cost and pricing data as required for government reporting.**
- ✓ **Do not attempt to represent Orthofix or otherwise reference the Orthofix name when making any public statements, unless you receive prior approval from the Compliance Committee.**

# ON-LABEL PRODUCT PROMOTION

The promotion of medical devices is highly regulated by the United States Food and Drug Administration (“FDA”) and various regulatory bodies in other countries in which Orthofix conducts business. The applicable laws and regulations are designed to make certain that the information that manufacturers provide to health care professionals and patients about the uses, benefits, and risks of medical devices is truthful, not misleading, and based on robust scientific evidence and sound clinical medicine. Among other things, these laws and regulations generally limit the promotion of a medical device to the cleared or approved uses of the device. As part of Orthofix’s commitment to operating ethically and lawfully, Orthofix employees and its contracted representatives must only promote its products for on-label uses.

## ***Obligations of Sales and Marketing Personnel***

All Orthofix sales and marketing personnel must be familiar with and understand the on-label uses of products for which they are responsible. They must also ensure that any third parties that are engaged to promote Orthofix products are familiar with and understand the on-label uses of any relevant products.

## ***Unsolicited Questions from Health Care Professionals (HCPs) Concerning Off-Label Uses of Orthofix Products***

When field representatives are questioned by HCPs concerning unapproved or uncleared uses of Orthofix products, all such unsolicited requests for the provision of information about the off-label use of Orthofix products shall be directed to the Orthofix Regulatory Affairs Department. Company responses will be prepared and disseminated by the Regulatory Affairs Department in accordance with guidance from the FDA or other authority. In recognition of the critical importance of patient safety, if a field representative

### **Your Responsibilities...**

- ✓ **Be familiar with and understand the on-label uses of the Orthofix products you sell and/or market.**
- ✓ **Only promote Orthofix products for on-label uses.**
- ✓ **Avoid answering questions from HCPs concerning unapproved or uncleared uses of Orthofix products.**
- ✓ **Refer all questions about off-label use of Orthofix products to Regulatory Affairs.**
- ✓ **Only use company approved materials in connection with the promotion of Orthofix products.**
- ✓ **Do not alter any of Orthofix approved promotional materials.**
- ✓ **Adhere to Orthofix’s on-label promotion policy.**

is put in a situation in which an HCP initiates a discussion regarding the functionality (e.g., manner of use, device characteristics, or operating parameters) of an Orthofix device for an off-label use in an immediate patient care setting (including immediately prior to a surgical procedure or during a surgical procedure), the field representative may describe the functionality of the Orthofix product for that use after notifying the HCP that the proposed use is off-label. The field representative may only describe information on device functionality on which the representative has been trained or which information has been provided to the field representative by the Company. Anecdotal information shall not be described. If an HCP initiates such a discussion other than in an immediate patient care setting, the field representative should offer to direct the inquiry to Regulatory Affairs. Under no circumstances should a field representative participate in a discussion about potential clinical outcomes of an off-label use or make reference to other information where the outcomes of such off-label use may be discussed. *Note: If an HCP initiates a discussion of an Orthofix device for an off-label use in an immediate patient care setting and the Orthofix representative provides input to the requesting HCP, this should be reported to the Orthofix Corporate Compliance Office at [compliance@orthofix.com](mailto:compliance@orthofix.com) to ensure this discussion is properly documented.*

### **Approval of Promotional Materials**

Only materials that have been approved by Orthofix's Regulatory Affairs and Legal Departments and Compliance Office may be used in connection with the promotion of Orthofix products. Both the alteration of Orthofix approved promotional materials and the use of home-made promotional materials that have not been reviewed and approved by Orthofix are prohibited.

### **Compliance**

All Orthofix employees and contracted business associates are responsible for complying with Orthofix's On-Label Promotion policy, and the President or executive in charge of each division, subsidiary or operating unit is responsible for ensuring that his or her employees know and comply with the policy. Violations of the policy will result in disciplinary action, up to and including termination of employment or cancellation of business associate contract. If you have questions about the policy, please contact the Orthofix Corporate Vice President of Regulatory Affairs.

# COPYRIGHT PROTECTION ©

Copyright laws protect the author or originator of certain literary or artistic works from the unauthorized reproduction or duplication of such works by others. Copyright protection extends to written materials, computer software, musical works, pictorial, graphic, and sculptural works, motion pictures, audiovisual works and sound recordings.

Employees must ensure that their actions (such as photocopying, copying of computer software, downloading of music or video) comply with the copyright laws. It is important to remember that most copyrighted material will have the symbol © somewhere on the work.

## Your Responsibilities...

- ✓ **Do not copy or reproduce any copyrighted materials.**
- ✓ **Obtain permission (usually in writing) before reproducing someone else's work.**
- ✓ **Check for proper software documentation before using programs or installing on system resources.**

# TRAINING PROGRAM AND EXPECTATIONS

We recognize that education and communication are the cornerstones of an effective compliance program. To support this commitment, Orthofix has developed an important training program for employees so that each of us is familiar with the Code, the Compliance Program policies and procedures, our U.S. HIPAA policies and procedures and other laws, regulations and requirements pertaining to our jobs.

At least once a year, every employee will be required to attend and/or complete the compliance training designated for his or her position. New employees will be required to complete the mandated training within the first thirty (30) days of employment. Additional training or refresher sessions may be conducted as the need arises.

## Your Responsibilities...

- ✓ **Work actively with your department to ensure compliance requirements are met and any concerns or questions are addressed.**
- ✓ **Attend and/or complete yearly Orthofix Compliance training.**
- ✓ **Make suggestions that would improve our training program.**
- ✓ **Verify your completion of training through the online learning management system.**

Failure to meet the Orthofix Compliance training requirements could result in disciplinary action, up to and including termination from employment or cancellation of business associate agreement.

# USING PERFORMANCE IMPROVEMENT TO ENHANCE COMPLIANCE

The goal of the Orthofix Compliance Program is to promote the highest level of honest and ethical business practices and to protect Orthofix's reputation and assets. Program objectives include: (1) communication of Orthofix commitment to the legal and regulatory requirements, (2) promotion of consistent adherence to internal policies and procedures, and (3) providing employees a framework for applying appropriate and ethical reasoning to business decision-making.

Orthofix has full confidence that its employees are committed to legal and ethical compliance. The Orthofix Compliance Program provides a framework to assure that education, training, and related expectations can be effectively communicated to officers, management, and employees alike.

The Orthofix Compliance Program is an evolving program designed to meet the needs of our employees and the organization in a changing regulatory environment. It is important for employees to play an active role so that we may continually improve compliance performance. We all have an important role in protecting the reputation and assets of Orthofix so that our mission can be accomplished.

## Your Responsibilities...

- ✓ **Understand the compliance obligations of your particular job function.**
- ✓ **Develop and communicate recommendations to continually improve compliance processes and outcomes.**
- ✓ **Promptly report potential violations of any law, regulation, or the Code to your manager or contact the Compliance Hotline.**

# GETTING HELP AND REPORTING POTENTIAL VIOLATIONS

If you have any questions about or need help with any compliance or ethics related issue, you may contact your manager, or obtain more detailed information from the Corporate Compliance Manual's policies and procedures. Your manager should always be available to answer your compliance questions or discuss your concerns. He or she will keep your discussions confidential as appropriate. To discuss your concerns with someone else, or anonymously, Orthofix has set up a confidential telephone hotline for employees and associates who have any compliance questions, concerns or problems. The hotline may also be used for reporting suspected violations of this Code of Conduct, the Corporate Compliance Program, Orthofix policies and other laws and regulations. **Employees and contracted business associates have an obligation to report immediately any suspected violations of the Code of Conduct or other irregularities to their manager, the confidential hotline, Compliance Committee Members or the Chief Compliance Officer.**

If you need help, have a concern, or want to report a potential violation, take one or more of the following steps:

**Step 1** Consider communicating with your manager concerning your question or concern.

**Step 2** Call the Compliance Hotline: +1-855-603-6985 or via the internet at [www.orthofix.ethicspoint.com](http://www.orthofix.ethicspoint.com), and follow the on-screen instructions.

**Step 3** You may also ask your question or report suspected violations to the Company's Chief Compliance Officer or, for matters outside of the United States, to the Compliance professionals listed below who are located in Brazil and Verona.

## **Michael Spencer, Chief Compliance Officer**

Telephone: +1-214-937-2071;

Email: [MichaelSpencer@Orthofix.com](mailto:MichaelSpencer@Orthofix.com)

## **Orthofix Latin America and Asia:**

### **Roberto Heckmann, Compliance Department**

Telephone: +55 11 3087-2283;

Email: [Roberto.Heckmann@Orthofix.com.br](mailto:Roberto.Heckmann@Orthofix.com.br)

### **Your Responsibilities...**

- ✓ **Contact your manager, the Compliance Committee or Chief Compliance Officer about any questions you have regarding the Code.**
- ✓ **Promptly report violations of any law, regulations, the Code, or the Compliance Program to your manager, call the Compliance Hotline or contact the compliance committee.**
- ✓ **Include all information in your report necessary to ensure complete and accurate follow-up.**



**Orthofix Europe, the Middle East, and Africa:****Chiara Sandri, Compliance Department**

Telephone: +39 045 6719 079,

Email: [ChiaraSandri@orthofix.it](mailto:ChiaraSandri@orthofix.it)

You will find immediately below a brief explanation of the violation reporting procedure for the Code. As previously noted in the reporting procedures, in addition to the reporting provisions set forth in this Code, you may report a concern regarding accounting, internal controls or auditing matters directly to the Chair of the Audit and Finance Committee of the Company's Board of Directors. Additionally, you may report compliance related issues directly to the Chair of the Compliance Committee of the Company's Board of Directors. Such report may be made in a confidential anonymous submission directed to either Chairman at the following address:

Attention: Chairman, Audit and Finance Committee  
Board of Directors  
Address: 3451 Plano Parkway, Lewisville, TX 75056

Attention: Chairman, Compliance Committee  
Board of Directors  
Address: 3451 Plano Parkway, Lewisville, TX 75056

If you want, you may ask your questions or report suspected violations through the hotline without giving your name. After making a report, a follow-up investigation will take place, including corrective action when appropriate. **No Orthofix employee will be disciplined or terminated because he or she reports in good faith a suspected violation.** Please be aware, retaliation does not include appropriate disciplinary action against an employee who may have engaged in wrongdoing or who is not meeting expectations. Additionally, employees will not be exempt from the consequences of their wrongdoing by self-reporting.

# Reporting Procedure

Orthofix strives to apply high ethical, moral and legal principles in every aspect of business conduct. The Company intends to comply with all rules and regulations of federal, state, provincial and local governments, all appropriate private and public regulatory agencies and any provision of federal law relating to fraud against shareholders.

## ***Violation Reporting Procedure***

All employees are encouraged to report either orally or in writing to their immediate supervisor or alternate line of authority as hereinafter described, all evidence of activity by an Orthofix department or employee that may constitute:

- Instances of Corporate Fraud;
- Unethical Business Conduct; or,
- A violation of State, Federal, or Provincial law or
- Improper accounting or auditing matters, or
- Non-compliance with SEC rules and regulations.

Any Orthofix employee who in good faith reports such incidents as described above will be protected from threats of retaliation, discharge, or other types of discrimination including but not limited to compensation or terms and conditions of employment that are directly related to the disclosure of such reports. In addition, no employee may be adversely affected because the employee refused to carry out a directive which, in fact, constitutes corporate fraud or is a violation of State or Federal law.

Any employee who wants to report evidence of alleged improper activity as described should contact his/her immediate supervisor, or the supervisor's manager. In instances where the employee is not satisfied with the supervisor or manager's response, or is uncomfortable for any reason addressing such concerns to their supervisor or the manager of such supervisor, the employee may contact the Chief Compliance Officer. The contact information for the Chief Compliance Officer is shown below. Employees are encouraged to provide as much specific information as possible including names, dates, places, and events that took place, the employee's perception of why the incident(s) may be a violation, and what action the employee recommends be taken. Anonymous written or telephonic communications will be accepted. Employees who choose to identify themselves will receive a reply to their report within 20 working days or as soon as practicable thereafter.

## ***Non-Retaliation***

Retaliation against any person who voices a concern, files a complaint or participates in any subsequent related investigation is prohibited. It is unlawful to discharge, demote, suspend, threaten, harass or in any manner discriminate, in any term or condition of employment, against an employee who lawfully provides information or assists in a fraud-related investigation or proceeding involving issues outlined above. Employees or agents of Orthofix found to have engaged in retaliatory behavior may be subject to discipline up to and including termination.

Michael Spencer, Chief Compliance Officer

Telephone: +1-214-937-2071;

Email: [MichaelSpencer@Orthofix.com](mailto:MichaelSpencer@Orthofix.com)

# CODE OF CONDUCT

## Company Copy

### Orthofix Code of Conduct Certification

1. I have read and understand the Orthofix Code of Conduct;
2. I am not in violation of any of the policies of the Code of Conduct and I am not aware of any violation that has not been reported in accordance with the procedures set forth in the Code;
3. I understand that failure to comply with the Code of Conduct may result in disciplinary action for employees (including termination of employment), or termination of a contractual relationship with Orthofix for distributors or representatives, and that a violation of the Code of Conduct may also constitute a violation of law that may result in civil or criminal penalties for me and/or Orthofix. I will abide by and support the policies set forth in the Code of Conduct. I further understand that my agreement to comply with the Code of Conduct does not constitute a contract of employment for employees, distributors or representatives.

Employee Information:

\_\_\_\_\_  
First Name

\_\_\_\_\_  
Middle Initial

\_\_\_\_\_  
Last Name

\_\_\_\_\_  
Orthofix Department

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date

# CODE OF CONDUCT

## Employee Copy

### Orthofix Code of Conduct Certification

1. I have read and understand the Orthofix Code of Conduct;
2. I am not in violation of any of the policies of the Code of Conduct and I am not aware of any violation that has not been reported in accordance with the procedures set forth in the Code;
3. I understand that failure to comply with the Code of Conduct may result in disciplinary action for employees (including termination of employment), or termination of a contractual relationship with Orthofix for distributors or representatives, and that a violation of the Code of Conduct may also constitute a violation of law that may result in civil or criminal penalties for me and/or Orthofix. I will abide by and support the policies set forth in the Code of Conduct. I further understand that my agreement to comply with the Code of Conduct does not constitute a contract of employment for employees, distributors or representatives.

Employee Information:

\_\_\_\_\_  
First Name

\_\_\_\_\_  
Middle Initial

\_\_\_\_\_  
Last Name

\_\_\_\_\_  
Orthofix Department

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date