

# ORTHOFIX MEDICAL INC. COMPREHENSIVE COMPLIANCE PROGRAM

## I. INTRODUCTION

Orthofix Medical Inc. (“Orthofix” or “Company”) is committed to establishing and maintaining an effective compliance program in accordance with the Compliance Program Guidance which was published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”). Orthofix’s compliance program, established by its Board of Directors in conjunction with Orthofix senior management, is one of the key components of the Company’s commitment to conduct business with the highest standards of ethical practice. This comprehensive compliance plan (“CCP”) is part of Orthofix’s broader compliance program.

The purpose of Orthofix’s compliance program and of this CCP is to prevent, detect and correct violations of law or Company policy, while encouraging and fostering an ethical corporate culture. As the HHS-OIG Guidance recognizes, the implementation of such a program cannot guarantee that improper conduct will be entirely eliminated, it is Orthofix’s expectation that all Orthofix officers, managers and employees (collectively, “Employees”), and other applicable third parties engaged by the Company (collectively, “Agents”) will comply with the Company’s Corporate Code of Conduct (the “Code”), and the relevant policies and work instructions established in support of the Code. In the event that Orthofix becomes aware of potential violations of law, the Code or Company policy, the Company will, where appropriate, investigate the matter and take disciplinary action and implement corrective measures to prevent future violations.

This CCP incorporates fundamental elements of Orthofix’s compliance program, which was tailored to fit the size of the Company and the nature of Orthofix’s business as a medical device manufacturer. It is a dynamic program, involving not only multiple policies and work instructions, but also the commitment of senior management and the support of all Employees and Agents to make the program effective.

## II. OVERVIEW OF COMPLIANCE PROGRAM

### 1. Written Standards.

- Orthofix’s Code provides the foundational standards and expectations of behavior for its workplace. The Code establishes that Orthofix expects its Employees and Agents to act in accordance with law and applicable Company policy. The Code articulates Orthofix’s fundamental principles, values and framework for action within the organization.
- The HHS-OIG Guidance has identified several potential risk areas for medical device manufacturers and called on companies to develop compliance policies to address these risk areas. As relevant to medical device manufacturers, these risk areas include (1) data integrity

pertaining to government reimbursement practices, and (2) kickbacks and other illegal remuneration.

- Orthofix has adopted written policies and work instructions to implement its high ethical standards and meet its healthcare compliance obligations under applicable laws, regulations and industry codes of conduct. Many of these policies and work instructions specifically address guidance for conducting business with health care professionals (“HCPs”), including (i) placing a specific annual dollar limit on the provision of gifts, and promotional materials; (ii) addressing the proper distribution of Orthofix products for use in connection with evaluation and demonstration purposes; (iii) outlining guidelines for the provision of consulting services to ensure each payment to an HCP does not exceed the fair market value for their services rendered; and (iv) the appropriate provision of grants and charitable contributions.

## **2. Leadership and Structure**

- **Compliance Officer.** Orthofix has designated Jill A. Mason as its Chief Ethics and Compliance Officer (“CECO”). Ms. Mason is charged with the responsibility for developing, operating and monitoring Orthofix’s compliance program. Company management works with the CECO and other Compliance Department members to ensure the Company effectively prevents, detects and reacts to instances of non-compliance.
- **Compliance Committee.** Orthofix has established a Compliance Committee of the Board of Directors and an Executive Compliance Committee to advise the CECO and assist in the implementation of the Company’s compliance program.

## **3. Education and Training.**

A critical element of Orthofix’s compliance program is the education and training of Employees and Agents on the Company’s legal and ethical obligations under applicable federal health care program requirements. Orthofix is committed to effectively communicating its standards and procedures to all affected Employees and Agents. Moreover, Orthofix regularly reviews and updates its training programs, as well as identifies additional areas of training on an “as-needed” basis.

## **4. Open Lines of Communication.**

Orthofix is committed to fostering dialogue between management and Employees and Agents. The Company’s goal is that, when seeking answers to questions or reporting potential instances of compliance violations, all Employees and Agents should know who to contact and know

that they are able to do so without fear of retaliation. To that end, Orthofix has adopted open-door practices, as well as those of confidentiality and non-retaliation. In order to further encourage open lines of communication regarding potential compliance violations, Orthofix has established a toll-free and online compliance hotline to allow individuals to raise concerns of potential misconduct. Reports may be made anonymously through this service if the reporter so desires.

## **5. Enforcement.**

When allegations of misconduct are raised, they are promptly reviewed and investigated, as necessary. Although specific activities associated with an investigation may vary based on the nature and circumstances of the issue, each is conducted using a consistent framework of principles. If a violation is found, Orthofix's compliance program includes clear disciplinary guidance and other policies that set out the consequences for violation of the law or Company policy. Although each situation is considered on a case-by-case basis, Orthofix consistently undertakes appropriate disciplinary action to address inappropriate conduct and deter future violations.

## **6. Auditing and Monitoring.**

Orthofix's compliance program includes efforts to monitor, audit and evaluate conformity with the Company's compliance policies and work instructions, including efforts to monitor the activities of Employees and Agents engaged in a sales force role. Orthofix notes that in accordance with HHS-OIG Guidance, the nature of its review, as well as the extent and frequency of the Company's compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. Orthofix utilizes ongoing assessment of compliance programs to identify new and emerging risk areas and address these risks.

## **7. Corrective Action Plans.**

A compliance program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, Orthofix's compliance program requires the Company to respond promptly to potential violations of law or Company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in the Company's policies, practices, or internal controls, and take action to prevent future violations.

## **ORTHOFIX MEDICAL INC., 2022 DECLARATION OF COMPLIANCE**

As part of Orthofix's continued efforts in the area of compliance, the Company has developed a CCP that is reasonably designed to prevent and detect violations. Consistent with the HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Orthofix has tailored its CCP to the nature of our business as a medical device manufacturer. The medical device industry has established, and Orthofix's CCP is designed in accordance with, a voluntary ethical code called the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"). The AdvaMed Code is substantially equivalent to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, but reflects the unique interactions between medical technology companies and HCPs.

Government standards on compliance programs recognize that no program can completely prevent individual Employees and Agents from improper conduct. Recognizing that compliance is a dynamic concept, Orthofix continuously reviews, updates and improves its CCP. As a result, the CCP periodically incorporates changes in policy and approach that require the subsequent development of new and upgraded systems and processes.

Orthofix has developed a CCP that the Company believes meets the compliance goals set forth by the State of California. The description of Orthofix's CCP outlined above reflects the plan Orthofix has implemented. To the Company's knowledge, Orthofix is, in all material respects, in compliance with its CCP and applicable law.

To request a copy of this CCP or this written declaration, please call 1-800-527-0404.