

OMCM 231/01

Organisational Model

**ORGANISATIONAL, MANAGEMENT AND CONTROL MODEL
PURSUANT TO LEGISLATIVE DECREE NO. 231 OF 8 JUNE 2001**

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Preamble

This Organisational, Management and Control Model (hereinafter also referred to as the "**Model**") contains a consistent system of principles, values, controls, operating instructions and ethical rules which Orthofix S.r.l. (the "**Company**" or "**Orthofix**") considers fundamental and irreplaceable for the conduct of all company activities, and of which it requires utmost compliance by members of corporate bodies and management, Company employees, and all those who work, even *de facto*, for the Company, including third parties such as, purely by way of example and not limited to, agents, contractors, consultants, etc. (the "**Recipients**").

The Company, in fact, considers that complying with (and cause that anyone liaising with it complies with) the highest standards of ethics and transparency takes precedence over any business need.

Orthofix, therefore, expects all those who have and intend to have legal relations with the Company to adopt a conduct that complies with the provisions of this Model and in line with the ethical principles contained herein.

This Organisational, Management and Control Model pursuant to Legislative Decree 231/01 consists of a summary document, which contains the general and special sections of the Model, and various Annexes, which form an integral part of the Model.

Components of the Model

01

General Section

It includes a brief examination of the regulatory provisions set forth in Legislative Decree 231/01 and the main practical implications that these provisions have and/or may have for Orthofix and all those who work with and/or for it, an indication of the offences giving rise to liability under the aforementioned decree ("predicate offences"), the regulation of Orthofix's Supervisory Body, a description of the disciplinary system adopted by the Company and the system of communication and training on the content of the Model.

02

Special Section

It contains the identification of the activities most exposed to the risk of predicate offences being committed, a description of the risk profile relating to each type of offence and an indication of the prevention and control tools adopted by the Company.

03

Annexes

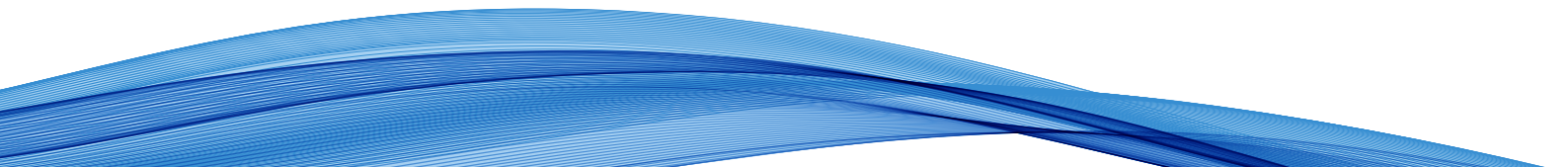
- Orthofix Group Corporate Code of Conduct and Addendum adopted by Orthofix S.r.l.
- Existing Processes, Procedures, Practices
- Functional chart
- Summary table of Predicate Offences and Sensitive Departments/Activities

Definitions

For the better understanding of this document, the definitions of the most important recurring terms are specified below:

Risk Areas	The areas of the Company's activities in the context of which, in practical terms, there is a risk of commission of Offences, as identified in the Special Part of the Model.
NCLA	The National Collective Labour Agreement applied by the Company.
Code of Ethics	The Code of Ethics adopted by the Orthofix Group and the Addendum to the Code of Ethics approved by the Company's Board of Directors.
External Parties	All third parties (self-employed or quasi-subordinate workers, professionals, consultants, agents, distributors, suppliers, business partners, etc.) who, by virtue of contractual relations, act on behalf of the Company.
Consultants	The parties acting in the name and/or on behalf of the Company under an engagement contract or other independent contractor relationship.
Recipients	Corporate Officers and External Parties.
Employees	Persons having an employment relationship with the Company, including executives, and those who, irrespective of the type of contract, nevertheless perform work with the Company.
Legislative Decree 231/2001 or the Decree	Legislative Decree No. 231 of 8 June 2001, as amended and supplemented.
Entities	Companies, consortia, etc.
Corporate Officers	Members of the Board of Directors, statutory auditors, liquidators, general manager, executives and employees of the Company.
Persons carrying out a public service	Pursuant to Article 358 of the Criminal Code, "persons carrying out a public service are those who, for any reason, perform a public service. Public service must be understood as an activity regulated in the same forms as the public function, but characterised by the lack of the powers typical of the latter, and with the exclusion of the carrying out of simple organisational tasks and the provision of purely practical work".
Guidelines	The "Guidelines for establishing an organisational, management and control model under article 6, paragraph 3 of Legislative Decree No. 231/01" approved by Confindustria on 7 March 2002 and subsequent amendments and additions.
Model	This Organisational, Management and Control Model, which contains the provisions adopted by Orthofix S.r.l. in compliance with Legislative Decree 231/2001 and its subsequent amendments.
Corporate Bodies	The Board of Directors, the Board of Statutory Auditors and their members.
Supervisory Body or SB	The internal control body in charge of supervising the functioning of the Model and compliance with it, as well as the updating of the Model.

Public Administration or "P.A."	The State (including governmental, territorial, local, sectorial entities, such as, governmental bodies, regulatory authorities, regions, provinces, municipalities, districts) and/or all public bodies and entities (and in cases determined by law or functions, private entities that nevertheless perform a public function, such as, for example, concessionaires, bodies governed by public law, awarding authorities, public-private mixed companies) that perform activities in pursuit of public interests and the public administration in the broad sense and administrative management function. This definition includes the Public Administration of Foreign States and of the European Union as well as, again in relation to Offences against the P.A., persons carrying out or in charge of a public service (under concessions or otherwise) or performing a public function and/or public officials. In this context, however, (i) public service includes, <i>inter alia</i> , activities carried out, under a concession or agreement, for a public general interest and subject to the supervision of public authorities, activities relating to the protection of or concerning life, health, welfare, education, etc. (ii) public function includes, <i>inter alia</i> , activities governed by public law, including the legislative, administrative and judicial functions of any public body.
Commercial Partners	Natural and/or legal persons cooperating with the Company under a contract.
Public Official	As provided under Article 357 of the Criminal Code, "for the purposes of criminal law, public officials are those who exercise a legislative, judicial or administrative public function. For the same purposes, an administrative function governed by public law and by authorising measures and characterised by the shaping and carrying out of the will of the public administration or by its performance by means of authoritative or certifying powers is public".
Offences	The types of offences to which the rules set out in Legislative Decree 231/2001 on the administrative liability of Entities apply.
Contact Person or "Representative"	The Corporate Officer of the Company who, by delegation of powers or organisational arrangement, is entrusted with the responsibility (severally or jointly with other persons) of specific functions and activities.
Company	Orthofix S.r.l.
Orthofix	Orthofix S.r.l.
Group	The corporate group headed by Orthofix Medical Inc., Lewisville, Texas.
ICLF	Legislative Decree No. 58 of 24 February 1998, as amended.



1. Legislative Decree No. 231/2001

1.1 The administrative liability regime for legal persons

The Decree, setting forth the “Rules on administrative liability of legal persons, companies and associations, including those without legal personality”, introduced into the Italian legal system a system of administrative liability for entities for offences that are exhaustively listed.

1.1.1 THE CONDITIONS FOR THE APPLICABILITY

For this liability to apply, it is necessary that:

- a) a **predicate offence** is committed by one of the following specific persons:
 - by natural persons who hold representative, administrative, management or control (including *de facto*) offices of the Entity or of organisational areas with financial and functional autonomy and who carry out, including *de facto*, the management and control of the Entity (“**top management**”);
 - by natural persons subject to the direction or supervision of the above-mentioned persons (“**subordinates**”)
- by **persons acting in the name and on behalf of the Entity** pursuant to a mandate and/or any cooperation agreement or engagement; and
- b) the offence was committed in its **interest or to its advantage**.

If the interest is missing altogether because the person committing the offence has acted only in its own interest or in the interest of third parties, the entity is not liable. On the contrary, if an interest of the entity - albeit partial or marginal - exists, the administrative liability regime is applicable even if no advantage has materialised for the entity, which may at most benefit from a reduction in the monetary sanction.

1.1.2 LIABILITY OF THE ENTITY AND INDIVIDUAL LIABILITY

The liability of the Entity is in addition to - and does not replace - the criminal liability of the natural person who materially committed the offence, and is independent of it, as it exists even when the perpetrator has not been identified or cannot be criminally charged or when the offence can no longer be prosecuted for a reason other than amnesty.

It should be noted that Legislative Decree No. 231/2001 does not introduce new offences with respect to those existing and envisaged for natural persons, but extends, for the cases expressly indicated and in accordance with the particular rules laid down therein, the liability also to the Entities to which the aforesaid natural persons are functionally referable. It is, therefore, a (again, “administrative”) liability that is in addition to - and does not replace - the criminal liability of the perpetrator.

The basis of this liability consists, in a nutshell, in an “organisational fault” of the Entity. The latter, in fact, is held liable for the administrative offence deriving from the Offence committed by a person within the entity, if it has failed to set up an organisation capable of effectively preventing such offences from being committed (or in any event of significantly reducing the possibility thereof) and, in particular, if it has failed to set up an internal control system and adequate procedures for carrying out the activities at greater risk of commission of the Offences (for example, in the context of contracting with the Public Administration) provided for by the Decree.

1.1.3 THE BURDEN OF PROOF

In particular, the Entity's liability is presumed if the offence is committed by a natural person who holds a position of top management or responsibility; consequently, the Entity bears the burden of proving its extraneousness to the facts by proving that the act committed is outside the company's policy.

Conversely, the Entity's liability shall be proved in the event that the person who committed the offence does not hold a top management position within the company's organisational system; the burden of proof then falls on the public prosecution, which must prove the existence of organisational or supervisory deficiencies that may entail co-liability on the part of top management.

1.1.4 PREDICATE OFFENCES

The offences entailing the liability of the Entity are exhaustively indicated by the legislator, and are subject to frequent and periodic amendments and additions by the same; therefore, constant verification of the adequacy of the system of rules constituting the organisational, management and control model provided for by the Decree and functional for the prevention of such offences is necessary.

Moreover, the scope of application of the administrative liability of Entities is set to be further increased, but, in any case, these groups can be identified in the following (for a more detailed description of each of them, please refer to the [Annex List of Offences](#)):

Predicate Offence Categories	Icon
Offences committed against the Public Administration (Articles 24, 25 and 25 <i>decies</i> of the Decree)	
Cyber offences and unlawful processing of data (Article 24 bis of the Decree)	
Offences relating to counterfeiting money, other legal tender and revenue stamps (Article 25 bis of the Decree)	
offences against industry and trade (Article 25 bis 1 of the Decree)	
Corporate offences (Article 25 ter of the Decree)	
Bribery among private individuals (Article 25 ter, paragraph 1, letter s-bis of the Decree)	
Offences for the purpose of terrorism or subversion of the democratic order provided for in the Criminal Code and in special laws and offences committed in violation of the provisions of Article 2 of the International Convention for the Suppression of the Financing of Terrorism, signed in New York on 9.12.1999 (Article 25 quater of the Decree)	
Offences relating to enslavement or maintaining slavery or servitude, human trafficking and the purchase and sale of slaves (Article 25 quinquies of the Decree)	
Market abuses (Article 25 sexies of the Decree)	
Manslaughter and grievous or very grievous bodily harm, committed in breach of the rules on accident prevention and protection of workplace hygiene and health (Article 25 septies of the Decree)	
Handling stolen goods, laundering and use of money, goods or benefits of illegal origin, self-laundering (Article 25 octies of the Decree)	
Offences relating to means of payment other than cash (Article 25 octies.1 of the Decree)	
Copyright infringement offences (Article 25 novies of the Decree):	
Environmental Offences (Article 25 undecies of the Decree):	
Employment of illegally staying third-country nationals (Article 25 duodecies of the Decree):	
Racism and Xenophobia (Article 25 terdecies of the Decree):	
Fraud in sports competitions, unlawful gambling and betting and games of chance using prohibited equipment (Article 25 quaterdecies of the Decree)	
Tax offences (Article 25 quinquiesdecies of the Decree)	
Transnational offences (extension of the Decree by introduction of Law 16 March 2006, No 146, Art. 10)	
Offences of smuggling (Article 25 sexesdecies of the Decree)	

1.1.5 THE SANCTIONS SYSTEM

The determination of the monetary sanctions to be imposed under the Decree is based on a **quota system**. For each offence, in fact, the law abstractly determines a minimum and a maximum number of quotas; **the number of quotas can never be less than one hundred and more than one thousand, and the amount of the individual quotas can range from a minimum of approximately EUR 258 to a maximum of approximately EUR 1,549**. On the basis of these coordinates, the judge, having ascertained the liability of the entity, determines the monetary sanction applicable in the specific case.

The determination of the number of quotas by the judge is commensurate with the seriousness of the offence, the degree of liability of the entity, and any activity carried out to remedy the consequences of the offence committed and to prevent others. On the other hand, the amount of the individual quotas is determined according to the economic and financial conditions of the entity, in order to ensure the effectiveness of the sanction. Confiscation (including for equivalent amounts) of the price or profit of the offence committed (except for the part that can be returned to the injured party) is always ordered upon conviction.

Where it is not possible to perform confiscation of the assets that directly constitute the price or profit of the offence, such confiscation may concern sums of money, assets or other benefits with value equivalent to the price or profit of the offence.

As a precautionary measure, seizure of items which, as they constitute the price or profit of the offence or their monetary equivalent and may thus be confiscated, may be ordered.

In the cases provided for by law, the criminal court may apply disqualification sanctions, which may be particularly punitive since they affect the entity's business activity.

1.1.6) OFFENCES COMMITTED ABROAD

Article 4 of the Decree also regulates offences committed abroad. It provides that entities having their head office in the territory of the State shall also be liable in respect of offences committed abroad in the cases and under the conditions provided for in Articles 7 to 10 of the Criminal Code, provided that the State of the place where the act was committed does not prosecute them.

Therefore, the entity may be prosecuted when:

- it has its head office, i.e. the actual place where administrative and management activities are carried out, which may also be different from the place where the company or registered office is located (entities having legal personality), or the place where the activity is carried out on a continuous basis (entities without legal personality), in Italy;

To this end, first of all, the express regulatory provision of the possibility of imposing a disqualification sanction following the commission of the predicate offence actually committed is required.

Furthermore, it is necessary that the offence committed by the member of top management procured a significant profit for the entity, that the offence committed by the subordinate has been caused or facilitated by serious organisational deficiencies, or that it was a repeated offence.

Disqualification sanctions may consist of:

- a) disqualification from the exercise of business activity;
- b) suspension or revocation of the authorisations, licenses or concessions involved in the commission of the offence;
- c) the prohibition to contract with governmental entities, except to obtain the performance of a public service;
- d) exclusion from benefits, loans, grants or subsidies and the possible revocation of those already granted;
- e) prohibition of advertising goods or services.

When a disqualification sanction is applied, the publication of **the conviction** in one or more newspapers, either in excerpts or in full, may be ordered by the Judge, together with the posting in the municipality where the Entity has its head office. Publication is carried out by the Court Registry at the expense of the Entity.

In cases in which the interruption of the Entity's activity could result in significant negative impact on employment and/or serious harm to the community (for entities performing a public service or a service of public necessity), the judge may order the continuation of the activity by a judicial commissioner in lieu of the disqualification sanction.

- the State of the place where the act was committed is not prosecuting the entity;
- the request of the Minister of Justice, to which punishability may be subject, is also referred to the entity itself.

These rules concern offences committed entirely abroad by top management or subordinates.

With regard to the scope of application of the provision in question, any entity incorporated abroad under the provisions of its domestic law which, however, has its management or its main purpose in Italy, is subject to Italian law - hence also to the Decree.

1.1.7 INCHOATE OFFENCES

The scope of application of the sanctioning system provided for by Legislative Decree 231/2001 operates even for inchoate offences (Article 26). Indeed, **the liability of the company may also arise if the predicate offence takes the form of an inchoate offence** (Article 26 of the Decree), i.e. when the person performs acts that are unequivocally suitable for committing the offence and the action is not carried out or the event does not occur (Article 56 of the Criminal Code).

In that case, the monetary and disqualification sanctions are reduced by between one third and one half. Furthermore, the entity is not liable when it voluntarily prevents the performance of the action or the occurrence of the event.

1.2 The Exemption from Liability

Article 6 of the Decree provides for a form of exemption from the Entity's liability for the offences envisaged if the Entity proves that it has adopted and effectively implemented, prior to the commission of the offence, an organisational and management model (hereinafter also referred to as the "**Model**") suitable for preventing offences of the type that has occurred and has appointed a **special independent body** to supervise compliance with and continuous updating of said model.

In particular, if the offence is committed by persons in "top management", i.e. who hold positions of representation, administration or management of the Entity or of one of its organisational units with financial and functional autonomy, as well as by persons who exercise, also *de facto*, the management and control thereof, the Entity shall not be liable if it proves that:

- an **organisational and management model** has been adopted to supervise the prevention of the offences provided for in the Decree;
- a body ("**Supervisory Body**" or "**SB**") of the Entity specifically entrusted with the duty of supervising the functioning and application of the Model has been appointed;
- the SB did not fail to or did not inadequately exercise supervision;
- the perpetrator fraudulently circumvented the supervisory and management system.

Where, on the other hand, the offence is committed by subordinates subject to the management or supervision of one of the above mentioned persons, the Entity is liable if the commission of the offence was made possible by failure to comply with the management and supervision obligations. These obligations are presumed to have been complied with if the Entity, prior to the commission of the offence, has adopted and effectively implemented a Model capable of preventing offences of the kind committed, according to an assessment that must necessarily be *ex ante*.

Exemption from Liability

Top Management

The Entity is not liable for offences committed by a person in top management if it proves that:

- A Model has been adopted
- A Supervisory Body (SB) has been appointed
- the Supervisory Body did not fail to or did not inadequately exercise supervision
- The perpetrator fraudulently circumvented the supervisory and management system

Subordinates

For offences committed by persons subject to the management or supervision of one of the persons in top management, the Entity is liable if the commission of the offence was made possible by failure to comply with the management and supervision obligations.

These obligations are presumed to have been complied with if the Entity, prior to the commission of the offence, has adopted and effectively implemented a Model capable of preventing offences of the kind committed, according to an assessment that must necessarily be *ex ante*.

1.2.1 THE SUITABILITY OF THE MODEL

Said model shall provide, in relation to the nature and size of the organization as well as the type of activity carried out, suitable measures to ensure that the performance of the activities is in compliance with the law and to promptly discover and eliminate situations involving risk.

Therefore, the effective implementation of the model requires:

- a) periodic audits and possible modification of the model if significant violations of the provisions are discovered or if there are changes in the organisation or in the activity;
- b) a disciplinary system suitable for sanctioning failure to comply with the measures indicated in the Model.

1.2.2 THE VOLUNTARY BASIS OF THE MODEL

Adoption of the Model is optional and not mandatory. Consequently, any failure to adopt it is not subject to any sanctions, but exposes the Entity to administrative liability resulting from offences committed by top management or subordinates.

The adoption of a suitable Model and its effective implementation therefore become essential in order to be able to benefit from this sort of "shield", i.e. as an indispensable prerequisite to benefit from the exemption provided for by the legislator.

1.2.3 THE MODEL AS A DYNAMIC SYSTEM

Moreover, it is important to bear in mind that the Model is not to be understood as a static tool, but must be considered, on the contrary, a dynamic apparatus that allows the Entity to eliminate, through a correct and targeted implementation of the same over time, any shortcomings that, at the time of its creation, could not be identified.

Therefore, the Decree provides that the aforementioned Model **must**:

- identify the areas in which one of the predicate offences may occur;
- identify specific protocols to plan the training and implementation of the Entity's decisions in relation to the offences to be prevented;
- identifying methods through which financial resources are to be managed to prevent the commission of said offences;
- provide for obligations to and from the internal Supervisory Body responsible for monitoring the effectiveness of and compliance with the Model;
- provide, with reference to the size, structures and activities of the company's organisation, procedures suitable to allow for the correct fulfilment of the law in relation to the performance of company activities, to identify and eliminate the relevant possibilities or risks;
- provide a periodic audit and possible modification of the Model when significant violations of the provisions are discovered or when changes occur in the Entity's organisation or activity (updating of the Model);
- set up an internal disciplinary system capable of sanctioning any non-compliance with the measures indicated in the Model;
- provide for two or more channels, of which at least one is computerised, enabling the Recipients to submit, for the protection of the entity's integrity, circumstantiated reports of unlawful conduct, or of violations of the Model of which they have become aware by reason of their duties. Said channels must ensure the confidentiality of the identity of the whistleblower in the management of the report.

1.2.4 THE MODEL MUST REFLECT THE ORGANISATION AND MUST BE IMPLEMENTED IN PRACTICE

The adoption of the Model must necessarily be completed by its **effective and concrete implementation** and its **updating** and development aimed at maintaining compliance with the law and discovering risk situations in a timely manner, taking into account the type of activity carried out as well as the nature and size of the organisation. Indeed, the effective implementation of the Model requires **periodic audit** and its amendment if significant violations of the legal requirements are discovered or upon occurrence of significant changes in the organisation;

the existence of an appropriate disciplinary system is also relevant.

It should be noted that the Company's Model has also been prepared on the basis of the Guidelines drawn up by Confindustria and Confindustria Dispositivi Medici. However, it should be pointed out that the Guidelines are not binding and that the Models prepared by the Entities may deviate [from them] (without affecting their effectiveness) due to the need to adapt them to individual organisational realities.

2. The Organisational and Internal Control System

2.1 Objectives and Structure of the Organisational Model

2.1.1 THE ORTHOFIX GROUP

Orthofix Medical Inc., based in Lewisville, Texas, was founded in Verona, Italy, in 1980, on the intuition of orthopaedic researcher Giovanni De Bastiani, creator of the first external fixation device. Today, Orthofix Medical Inc. has evolved and grown to become one of the world's leading spinal and orthopaedic medical device companies, with more than 1,000 employees dedicated to the development, production, and distribution of multiple product lines in more than 60 countries around the world and offices in the United States, Italy, Germany, France, the United Kingdom, and Brazil. Link to company website: <https://www.orthofix.com/about/>.

The Orthofix Group, committed to improving patients' lives and providing innovative, quality-oriented solutions that enable healthcare professionals and organisations to meet the needs of their patients every day, has two strategic Business Units - Orthofix Spine and Orthofix Orthopedics. **Orthofix S.r.l.**, with head office in Verona, in particular, is the nerve centre of the latter.

2.1.2 THE ETHICAL BUSINESS MODEL

There is a strong belief at Orthofix that **compliance with laws** and an **ethical conduct** are not only necessary and morally correct, but are also an effective way of managing one's business, considering the context in which it operates. That being said, the Company - sensitive to the need to ensure conditions of correctness and transparency in the conduct of business and corporate activities, to protect its own position and image, the expectations of its shareholders and the work of its employees - considered that proceeding with the implementation of the Model envisaged by the Decree was in line with its corporate policies.

The Model, therefore, constitutes a valid awareness-raising tool for all those who work in the name and on behalf of Orthofix, in order for them to behave, in the performance of their activities and in the pursuit of their interests, correctly and straightforward, on the basis of procedures defined for the purpose of preventing the risk of commission of the offences set out in the Decree. The Company, in order to always guarantee conditions of correctness and transparency from an ethical and regulatory point of view, has deemed it appropriate to adopt an organisational and management Model capable of preventing the commission of the offences provided for in the Decree.

Considering the reference regulatory context in which it operates, as well as the system of controls to which it is subject, in defining the "organisational, management and control Model" the Company has adopted a design approach that allows it to use and integrate currently existing rules into said Model, forming, together with the **Code of Ethics**, a consistent *set of* internal rules and principles, aimed at disseminating a culture of ethics, correctness and legality.

In particular, through the adoption and constant updating of the Model, the Company intends to pursue the following main aims:

- rejects all forms of unlawful conduct by the Recipients of the Model, since they are contrary not only to the provisions of the law, but also to the ethical principles adopted by the Company;
- guarantee to the Company, by means of controls of corporate activities in the "areas of activity at risk", the concrete and effective possibility of timely intervention to prevent the commission of offences;
- specifically determine the "sensitive activities", i.e. those activities within the scope of which, due to their nature, the offences provided for in the Decree may be committed;
- guarantee to the Company, by means of controls of corporate activities in the "areas of activity at risk", the concrete and effective possibility of timely intervention to prevent the commission of offences.
- determine the general principles of conduct, to which specific procedures and protocols are added with reference to individual company functions;
- determine, in all those who act in the name of and operate on behalf of or in the interest of the Company (members of the Board of Directors, Company personnel, external contractors, partners, etc.), the awareness that they may incur disciplinary and/or contractual consequences, as well as criminal and administrative sanctions that may be imposed on them, in the event of violation of the provisions laid down in this regard;

- reiterate that any forms of unlawful conduct are strongly condemned by the Company, since even if the Company were apparently in a position to benefit from them, or if they were carried out in its interest, they are in any case contrary not only to the provisions of the law, but also to the ethical principles to which the Company intends to adhere in the performance of its business activities;
- provide adequate record keeping and traceability of relevant transactions;
- avoid the concentration of the management of an entire process on one person within the organisation;
- identify the processes for managing and controlling financial resources;
- identify a system of disciplinary sanctions applicable in the event of violation of the provisions contained in the Model in line with the Workers' Statute and the National Labour Agreement. The disciplinary system is implemented on the principles of adversarial process and proportionality within a framework of equal treatment of all the different categories of persons required to comply with the contents of the Model;
- entrusting the SB with the task of supervising the functioning of and compliance with the Model and proposing its update if there have been significant violations of the provisions or organisational changes or changes in the Company's activities;
- provide adequate training to Corporate Officers (including Employees) and Recipients in general, on the activities included in the Risk Areas (which may entail the risk of commission of Offences) and on the sanctions that may be imposed on them or on the Company as a result of the violation of the law or of the Company's internal provisions;
- disseminate and affirm a corporate culture based on legality, with the express repudiation by the Company of any conduct contrary to the law or internal provisions and, in particular, the provisions contained in this Model;
- disseminate a culture of control, which must preside over the achievement of the objectives that, over time, the Company sets for itself;
- provide for an efficient and balanced organisation of the company, with specific regard to the formation of decisions and their transparency, preventive and subsequent controls, as well as internal and external information;
- risk prevention through the implementation of specific procedural principles aimed at regulating the formation and correct implementation of corporate decisions in relation to the offences to be prevented.

2.1.3 THE RISK ASSESSMENT PROCESS

The adoption of the Model, as well as the subsequent updates, was preceded by an activity of detection of the areas of risk ("risk assessment") on the basis of the provisions of the Decree and the indications contained in the "Guidelines for the construction of organisational, management and control models pursuant to Legislative Decree 231/2001" drawn up by Confindustria. The purpose of this activity was to carry out a **preliminary mapping of the corporate functions and the related activities exposed to the risk of offences and to assess what actions should be taken to address the critical issues that have arisen.**

More specifically, the work carried out aimed, among other things, to analyse the current situation from the point of view of existing systems and procedures ("As is Analysis") and identify critical issues related to it ("Gap Analysis") in order to update the organisational, management

and control system of the Company to new business and legislative realities.

Therefore, in preparing and updating this Model, the regulations in force, the procedures and the control systems already in place and already operating within the Company have been considered, insofar as they are in part already suitable for reducing the risks of commission of offences and unlawful conduct in general, including therefore also those provided for by the Decree.

The Model consists of a General Section and a Special Section, the latter in turn subdivided into different sections (numbered by letters), referring to the different types of Offences considered relevant for the purposes of the Decree with reference to the Company's Business Activities.

2.2 Sources of the Model

The sources used by the Company as a reference in preparing the Model are indicated below:

- a) **Legislative Decree No. 231/2001 and subsequent amendments and additions.** In particular, it was taken into account that, pursuant to Art. 6(2) of Legislative Decree no. 231/01, the Model must meet the following requirements:
 - identify the activities within the scope of which there is a risk of offences being committed;
 - provide specific protocols to plan training and implementation of the entity's decisions in order to prevent the commission of Offences;
 - determine methods of managing financial resources suitable for preventing the commission of offences;
 - provide for information obligations vis-à-vis the Supervisory Body;
 - set up an internal disciplinary system capable of sanctioning any non-compliance with the measures indicated in the Model;
- b) **"Guidelines for the construction of organisational, management and control models pursuant to Legislative Decree No. 231/2001"** by **Confindustria Dispositivi Medici (formerly Assobiomedica)**;
- c) **"Guidelines for the construction of organisational, management and control models pursuant to Legislative Decree No. 231/2001"** by **Confindustria**;
- d) **Case law** on Legislative Decree 231/01: in preparing the Model, consideration was also given to the rulings that have been issued in these years with regard to administrative liability of Entities and that have highlighted many aspects considered essential for the purpose of drawing up a suitable Model.

3. The Risk Assessment Methodology

3.1.1 RISK ASSESSMENT PROCESS

The preparation of this Model was preceded by a series of preparatory activities divided into different phases, all aimed at setting up a risk prevention and management system, in line with the provisions of Legislative Decree no. 231/01 and industry best practices.

More specifically, for the purposes of adopting the Model, the Company carried out a risk assessment in order to:

1. enable the Company to adopt the most suitable protocols to prevent offences in the areas of activity deemed to be at risk; and
2. enable the SB to identify the activities on which to focus its audit activities.

The risk assessment was carried out by means of individual interviews with the persons responsible for company processes ("process owners"), as well as by examining relevant internal documents and the company organisational chart, with the aim of identifying:

1. the company processes which, theoretically, are at risk of offences being committed;
2. the specific activities, for each identified process, in which one or more unlawful behaviours may occur;
3. the Function within which this activity takes place;
4. the offences potentially associated with each activity at risk;
5. existing controls within the identified activities.

3.1.2 RISK ASSESSMENT

A risk assessment was then carried out, identifying for each **activity at risk**:

- the "inherent" risk, understood as the level of risk theoretically linked to each business activity, regardless of the existence of safeguards in place to mitigate that risk
- the effectiveness of the control system in preventing the risks theoretically present in the identified processes;
- the "residual" risk, which represents the level of risk determined taking into account the mitigating effect of the control system in place.

In this regard, the level of **inherent risk** was identified on the basis of the following quantitative indices:

- Probability**, understood as the frequency with which a given activity is performed in the Company's business, according to the scale below:

Scale	Classification	Description
1	Low/episodic frequency	The activity is carried out in exceptional circumstances, without a defined periodicity
2	Average/periodic frequency	The activity is carried out with a predetermined or determinable periodicity
3	High/continuous frequency	The activity takes place constantly/with significant frequency

- Impact**, understood as the seriousness of the consequences in the event of the commission of one of the predicate offences linked to the activity in question:

Scale	Classification	Description
1	Low	Monetary sanction of up to 500 quotas
2	Medium	Monetary sanction exceeding 500 quotas
3	High	Disqualification sanction

These quantitative indices were weighted, where necessary, by a qualitative assessment of the severity of the inherent risk.

Following the inherent risk, the **overall effectiveness of the control system** in place for each risk activity considered in mitigating the existing inherent risks was assessed, taking into account:

- the compliance of the process with established best practices;
- the existence of written procedures, manuals or directives governing the activity in question;
- the existence of computer tools or other instruments for the automatic control of activities;
- the existence and level of a segregation of duties within the process;
- the existence of formalised powers and first-level controls within the process.

Based on the assessment of the above parameters, the overall effectiveness of the control system for each relevant activity was classified as **low**, **medium** or **high**.

The level of **“residual risk”** was determined starting from the inherent risk identified as above and considering the mitigating effect of the existing control system, according to the diagram below:

		Effectiveness of the Control System		
		High	Average	Low
INHERENT RISK	Low	Low risk	Low risk	Low risk
	Medium	Medium risk	Medium risk	Medium risk
	High	High risk	High risk	High risk

3.1.3 GAP ANALYSIS AND RISK CONTROL

On the basis of the risk assessment as described above and, more specifically, of the effectiveness of the existing control system compared to industry best practices, the Company has identified areas for possible further improvement, immediately implementing the necessary measures and adopting adequate control plans to govern the residual risks, as well as a process of continuous improvement of the control system, which may be subject to periodic audit by the Supervisory Body, also in light of a periodic review of the level of residual risk as a result of the constant improvement of the effectiveness of the control system.

4. Adoption of the Model

4.1 Adoption and implementation of the Model

This document is **“a deed issued by the Managing Body”** in accordance with the provisions of the Decree, and therefore its adoption, any amendments to it, and the responsibility for its concrete implementation, are a duty of the **Company's Board of Directors**.

4.2 Recipients of the Model

The Model and the provisions contained and referred to therein must be complied with by the following persons (“Recipients”):

- Corporate Officers
- Employees
- External Parties

With regard to External Parties, compliance with the Model is ensured by means of a contractual clause obliging the contractor to abide by the principles of the Code of Ethics and the Model adopted by the Company, and to report any commission of offences or the violation thereof (see paragraph 5.8 below).

4.3 Updating the Model

4.3.1 UPDATE NEEDED

Updating the Model is necessary upon:

- introduction of new legislation;
- significant cases of violation of the Model and/or outcomes of audits on its effectiveness or experiences in the public domain within the industry;
- organisational changes in the company's structure or business sectors.

4.3.2 PERIODIC UPDATE

Updating must be performed cyclically and continuously, and the duty of formally arranging and implementing the updating or adaptation of the Model is entrusted to the Board of Directors, with the cooperation of the Supervisory Body.

More specifically:

- the Supervisory Body notifies the Board of Directors of any information of which it is aware that may determine that it would be appropriate to update the Model;

- the update programme is prepared by the Company, in agreement with the Supervisory Body and with the contribution of the corporate functions concerned;
- the Supervisory Body monitors the implementation of the actions ordered and informs the Board of Directors of the outcome of the activities.

Amendments and additions are reserved matters of the Board of Directors of the Company.

4.3.3 CHANGES TO IMPLEMENTATION PROTOCOLS

Amendments that concern the implementation protocols of the Model (e.g. procedures) are adopted directly by the corporate functions concerned, possibly also

after consulting the Supervisory Body, which may express an opinion and make proposals to that effect.

5. The Supervisory Body (SB)

5.1 Establishment

Pursuant to Article 6(1)(b) of Legislative Decree No. 231/2001, the Company, by resolution of the Board of Directors, set up the Supervisory Body (SB), which is entrusted with the duty of supervising the operation of and compliance with the Model and taking care of its updating.

5.1.1 AUTONOMY OF INITIATIVE AND CONTROL OF THE SUPERVISORY BODY

Pursuant to Article 6(1)(b) of Legislative Decree 231/2001, the Supervisory Body has “**autonomous powers of initiative and control**”.

The Supervisory Body operates with appropriate autonomy and reports to the **Board of Directors** and/or the **Board of Statutory Auditors**, availing itself of the support of those corporate functions that from time to time may be useful for its activities.

5.2 Appointment and Requirements

5.2.1 TERM OF OFFICE OF THE SB

The SB holds office for three years and its members can be confirmed in office at the end of their term.

In the event that any member of the Supervisory Body ceases from its office for any reason, the Board of Directors shall, without delay, provide for the replacement by means of a specific resolution. The member

of the SB who is ceasing from their office shall, however, be required to exercise

all the functions provided for by law or by the Model until the person who will be appointed by the Board of Directors to replace them takes office. The person appointed as a replacement holds office for as long as the person replaced would have held office.

5.2.2 COMPOSITION OF THE SB

In accordance with the Guidelines, the Company's SB may be composed of one or more members, as decided by the Company's Board of Directors. In the case of a single member, the office must be held by

a person who is not part of the Company's organisation. If the Company opts for a multi-member composition, the majority of the members must be chosen among persons who are not part of the Company's organisation.

5.2.3 REQUIREMENTS OF THE SB

The SB as a whole, whether composed by a single member or with more than one member, must meet the requirements of:

- **autonomy and independence:** the position of the Supervisory Body within the Entity must guarantee the autonomy of the control initiative from any form of interference and/or conditioning by any body of the Entity, including the managing body. This autonomy is to be understood as not merely formal, i.e. it is necessary that the SB:
 - has effective powers of inspection and control;
 - has access to relevant company information;
 - is endowed with adequate resources (including financial resources);
 - can make use of tools, supports and experts in the performance of its monitoring activities.

The Supervisory Body must then be hierarchically independent: its members must neither be directly involved in management activities, nor hold executive functions within the Company, which, by making them participants in operational decisions and activities, would undermine their objectivity of judgement when verifying conducts and auditing the Model.

The members of the SB must not be linked to the management of the Entity or to the Entity itself by any parental ties, by significant economic interests (e.g. shareholdings) or by any situation that could generate even only potential conflicts of interest;

- **professionalism:** the members of the SB must have specific knowledge in relation to the techniques useful to prevent the commission of offences, to discover those already committed and to identify their causes, as well as to verify compliance with the Model and, when necessary, propose the necessary updates to the Model. The external members must possess, on the whole, adequate professionalism in legal-criminal and economic-business matters;

- b) those who have been notified a decree ordering them to stand trial for one of the offences or administrative offences referred to in the Decree;
- c) those against whom one of the preventive measures provided for in Article 10(3) of Law No. 575 of 31 May 1965, as replaced by Article 3 of Law No. 55 of 19

- **continuity of action**, to be developed by means of a structure dedicated to constant supervision of compliance with the Model, capable of constantly verifying the effectiveness and efficacy of the Model and providing for its continuous updating.

Furthermore, the individual members of the Supervisory Body must meet the requirements of professionalism and **integrity**. More specifically, the following persons shall not be appointed as members of the Supervisory Body:

- (a) those who have been sentenced, even if the conviction is not final or if they are on probation, or pursuant to a judgement issued under Articles 444 et seq. of the Code of Criminal Procedure, without prejudice to the effects of rehabilitation:
 - to imprisonment for a time of not less than one year for one of the offences provided for in Royal Decree 267 of 16 March 1942;
 - to imprisonment for a time of not less than one year, for offences punished under provisions regulating activities in the banking, securities, financial or insurance sectors and those governing securities and securities markets, payment instruments;
 - to imprisonment for a time of not less than one year for an offence against the public administration, against public trust, against property, against the public economy, for an offence relating to tax matters;
 - to imprisonment for not less than one year for any offence with criminal intent;
 - for one of the offences provided for in Title XI of Book V of the Italian Civil Code as amended by Legislative Decree No. 61/2002 and most recently amended by Law 69/2015;
 - for an offence which results in and has resulted in a conviction to a punishment leading to disqualification, including temporary disqualification, from public office, or temporary disqualification from management offices of legal persons and companies;
 - for one of the offences or administrative offences referred to in the Decree, even if sentenced to lesser punishment than that indicated in the preceding points;

March 1990, No 55, as amended, has been applied with a final decision.

Candidates for the office of members of the Supervisory Body must self-certify that they do not meet any of the conditions of ineligibility indicated above, expressly undertaking to notify any changes to the content of such declarations.

5.3 Removal

The Board of Directors of the Company may remove the members of the SB only for **cause**.

The following constitute **cause for removal**:

- significant failures to comply with the mandate conferred, with regard to the duties indicated in the Model, including breach of confidentiality obligations concerning the news and information acquired by reason of the mandate and negligence in pursuing the activities of control and updating of the Model;
- unjustified absence from three or more meetings of the SB, even if not consecutive;
- when the Board of Directors becomes aware of the aforesaid causes of ineligibility, prior to appointment as a member of the SB and not indicated in the self-certification;
- when the following grounds for termination from office occur.

5.4 Termination from Office

The members of the Supervisory Body shall cease to hold office the moment in which, following their appointment:

- find themselves in one of the situations contemplated in Article 2399 of the Italian Civil Code;
- lose the requirements of integrity mentioned above.

The members of the Supervisory Body may resign from office at any time, by giving at least two months' notice, without giving any reason.

5.5 Financial endowment of the SB

The SB is endowed with an **adequate financial budget** - decided annually by the Board of Directors on the proposal of the SB - which it may use to perform its functions; in the event of extraordinary needs requiring additional financial resources, the SB shall submit a specific request to the Board of Directors.

Any remuneration due to the members of the Supervisory Body (including the Chairman) is set forth at the time of appointment or by subsequent decision of the Board of Directors, after consulting the Board of Statutory Auditors. The members of the SB are also entitled to reimbursement of expenses incurred in connection with their office.

5.6 Duties and Responsibilities

Generally, the SB carries out two types of activities aimed at reasonably reducing the risks of offences being committed:

- **monitor** that the Recipients of the Model, specifically identified on the basis of the different offences and relevant processes identified, comply with the provisions contained therein;
- **verify** the results achieved by the application of the Model with regard to the prevention of offences and assess the need or appropriateness of adapting the Model to new regulations or new company requirements.

As a result of these audits, the SB will propose to the competent bodies any adjustments and updates to the Model that it deems appropriate: it must therefore be promptly informed of any changes to both the Model and the corporate structure of the Company.

5.6.1 ACTIVITIES OF THE SUPERVISORY BODY

From an operational point of view, the SB has the duty of:

- carry out periodic actions, on the basis of an annual or multiannual programme drawn up by the SB itself, aimed at verifying the provisions of the Model and, in particular, monitor:
 - a) that the procedures and controls envisaged by the Model are applied and documented in a compliant manner;
 - b) that ethical principles are complied with;
 - c) the adequacy and effectiveness of the Model in preventing offences relevant to the Decree.
- report any shortcomings/inadequacies of the Model in the prevention of offences relevant for the purposes of the Decree and verify that the management implements corrective measures;
- suggest appropriate verification procedures, always bearing in mind, however, that the responsibility for controlling activities lies with management;
- initiate internal investigations in the event of evidence or suspicion of a breach of the Model or commission of offences, as provided for in paragraph 8 below;
- periodically verify compliance with the procedures underlying the adoption of the most significant corporate actions and the execution of material contracts entered into by the Company in the areas at risk;
- promote initiatives to spread knowledge and effective understanding of the Model among the Recipients, ensuring the preparation of internal documentation (instructions, clarifications, updates) or specific training seminars, necessary for the Model to be understood and applied, in accordance with the provisions of paragraph 6 below;
- coordinating with the heads of the various corporate functions for the control of activities in the areas at risk and discussing with them all issues relating to the implementation of the Model (e.g. definition of standard clauses for contracts, organisation of courses for personnel, new relations with the Public Administration, etc.);
- suggest to the Board of Directors the necessary updates to the Model, so that it can be adapted to new regulations or organisational changes in the Company;
- request the periodic updating of the risk map, and verify its actual update through periodic targeted audits of risk activities. To this end, the SB must receive reports from management and from those in charge of control activities of any situations that may expose the Company to the risk of offences;
- collect, process and store all relevant information received concerning compliance with the Model.

5.6.2 FREE ACCESS TO INFORMATION BY THE SUPERVISORY BODY

For the proper performance of its duties, the SB shall:

- have free access, without the need for any prior consent, to persons and to all company documentation (documents and data), as well as the possibility of acquiring relevant data and information (financial, asset, economic transactions and all those transactions that more generally concern the management of the company) from the persons in charge; to this end, the Supervisory Body may request from the various company structures, including top management, all the information deemed necessary for the performance of its activities;
- have the right, coordinating with and informing in advance the corporate functions concerned, to request and/or engage third parties with the necessary specific skills, tasks of a technical nature;
- issue rules governing the schedule of activities and arrangements for meetings and information management;
- meet at least four times a year and as often as deemed necessary or urgent; the meetings will be recorded in minutes and copies of the same will be kept by the SB.

5.6.3 RESPONSIBILITY FOR THE FUNCTIONING AND EFFECTIVENESS OF THE MODEL

Without prejudice to the Board of Directors being responsible for supervising the adequacy of the SB's activity, since the management body bears ultimate responsibility for the functioning (and effectiveness) of the Model, the activities performed by the Supervisory Body cannot

be questioned by any other corporate body and structure.

The SB may be supported in carrying out its activities by a secretary, who is not entitled to vote at SB meetings.

5.7 Reporting to Corporate Bodies

The Supervisory Body of Orthofix is responsible for informing the corporate bodies, specifically:

- the Supervisory Body prepares **half-yearly reports**
 - 1) by the time the draft financial statements are approved by the Board of Directors;
 - 2) by the time of approval of the half-yearly management report pursuant to Article 2381, Section 5 of the Italian Civil Code
- The half-yearly report addressed to the Board of Directors and the Board of Statutory Auditors contains:
 - summary of all the activities carried out during the six-month reporting period and the checks and audits performed;
 - possible updating of the Model;
 - other topics of major importance;
 - plan of activities planned for the following six-month period
- the Supervisory Body maintains a **continuous line of communication** directly with the Chairman and the Managing Director in order to promptly report violations of the Model or request attention to critical issues relating to the functioning of and compliance with the Model.

The Board of Directors may convene the Supervisory Body at any time to report on its activities and request to consult with it.

5.8 Communications to the SB

5.8.1 COMMUNICATIONS CONCERNING SENSITIVE AREAS

In order to allow the Supervisory Body to monitor the adequacy and functioning of the Model, a communication system has been implemented between the Company and the SB concerning all sensitive areas, as identified in the Special Section.

The purpose of the system of communications to the SB is to enable it to constantly acquire relevant information on all sensitive areas.

The system implemented by the Company provides for two different forms of communication to the SB:

- **Whistleblowing**
- **Information flows**

5.8.2 REPORTS (" WHISTLEBLOWING) AND THEIR EVALUATION PROCEDURE

Each Recipient is required to make known, as promptly as possible, any problems or critical issues encountered in the application of the provisions of the Model.

More specifically, the following must be reported:

- unlawful conduct constituting one or more offences from which the entity may incur liability under Legislative Decree 231/01;
- conduct which, although not constituting an offence, has been committed in breach of the rules of ethics and conduct, procedures, protocols or provisions contained in the Model or in the Company's Code of Ethics.

The report, sufficiently detailed, must be made by providing the following information, together with any supporting documentation:

- Name of the reporting person;
- Clear and complete description of the conduct, including omission, that is the subject matter of the report;
- The circumstances of time and place in which the reported facts were committed and the related conduct;
- Parties involved, company structures / organisational units involved;
- Any third parties involved or potentially harmed;
- Any other information that may provide useful feedback in establishing the reported facts.

Reports made for the mere purpose of retaliation or intimidation or unfounded reports made with intent or gross negligence shall be sanctioned. More specifically, sending any communication that proves to be unfounded on the basis of objective elements and that is, again on the basis of objective elements, made for the sole purpose of causing unfair harm to the reported person shall be sanctioned.

The Company, as well as all the persons involved in the management of the report, shall guarantee the utmost **confidentiality** on the persons and facts reported, using, to this end, criteria and methods of communication suitable to protect the identity and integrity of the persons mentioned in the reports, so that the person making the report is not subject to any form of retaliation, avoiding in any case the communication of the data acquired to third parties unconnected with the report management process governed by this procedure.

5.8.3 REPORTING CHANNELS

Reports can be submitted via:

- 1) E-mail address at ODV@orthofix.it, access to which is restricted to members of the SB; or
- 2) Ordinary mail to the address Bussolengo (VR), 37012, Via delle Nazioni, 9, marked "privileged and confidential", to the attention of the Supervisory Body;
- 3) as well as through available Group channels, such as, in particular:
 - the IT platform Ethics Point, at the link: <https://secure.ethicspoint.com/domain/media/en/gui/34657/index.html>;
 - the Corporate Hotline, toll-free number 800-786907 (from Italy);
 - the Compliance Department's dedicated e-mail address compliance@orthofix.com.

5.8.4 CHECKS ON REPORTS

On a half-yearly basis, the SB may send a communication to the Group Compliance function to receive an update on any relevant reports in relation to the Model and sent through the channels made available by the Group, also in order to assess whether it is appropriate to take any action.

With reference to the reports received directly by the Supervisory Body, the latter preliminarily verifies their relevance and *prima facie* case, in coordination with the Compliance function (which will inform the Group Compliance function, for appropriate coordination) and, if necessary, with the assistance of an external legal advisor, bound to confidentiality on the activities carried out.

The SB then registers, by means of an identification code/ name, the report, ensuring the traceability and correct archiving of the documentation also in subsequent phases.

Whistleblowers in good faith will be guaranteed against any form of retaliation, discrimination or penalisation.

Anonymous reports are allowed. However, they limit the Company's ability to carry out an effective verification of what has been reported, as it is impossible to establish a smooth information channel with the reporter. They will therefore only be examined if adequately substantiated and detailed and concerning potential wrongdoing or irregularities considered as serious. Relevant factors for assessing anonymous reporting include the credibility of the facts described and the possibility of verifying the truthfulness of the breach from reliable sources.

Although it is not possible to define the duration of the investigation beforehand, given the specificity of each case, the SB will promptly analyse the reports.

The SB **classifies reports** into:

- Irrelevant reports: in this case, the SB will inform the reporting party and dismiss the report;
- Report in bad faith: the SB sends the report to the Head of the Compliance Function and/or to the reporting party's line manager, so that they may consider whether to initiate any disciplinary proceedings;
- Substantiated reports: if the SB considers that there is sufficient evidence of potentially unlawful conduct or conduct in breach of the Model, such as to allow an investigation to be initiated, it initiates the evaluation phase.

The **evaluation phase** takes the form of carrying out targeted checks on the reports, enabling the identification, analysis and evaluation of the elements confirming the grounds of the reported facts.

In this phase, the SB, which acts in close coordination with the Compliance Function, may decide to use the assistance, if necessary, of further internal support figures and the corporate Functions identified according to the subject matter of the report, as well as external professionals.

The person/function in charge of carrying out the verification:

- must ensure that it is carried out in a fair and impartial manner; this implies that each person involved in the investigation can be informed - once the investigation has been completed - of the statements made and the evidence obtained against them and that they are put in a position to rebut said statement and evidence;
- may use the support of technical advisors (such as external professionals or Group in-house specialists) on matters that do not fall within its specific competence.

Information gathered in the course of the verification must be handled with due discretion and kept within the verification team.

Upon completion of the checks, a report must be issued which shall:

- summarise the course of the investigation;
- set out the conclusions reached and provide any supporting documentation;

5.8.5 INFORMATION FLOWS

The purpose of the information flow system implemented by the Company is to create a communication system between those responsible for activities potentially at risk and the SB that is structured, continuous and disseminated.

Information flows take the form of sending communications and/or documents to the SB in accordance with specific timeframes and methods.

- provide recommendations and suggest actions to be taken to remedy violations detected and ensure that they do not occur in the future;
- be addressed to the Board of Directors and the Board of Statutory Auditors of the Company.

The evaluation phase can be concluded with:

- negative outcome, in which case the report is closed;
- positive outcome: in this case, the SB, through the Compliance Function, sends the outcome of the checks carried out to the Board of Directors, in order to allow the Company to adopt the necessary measures and any disciplinary sanctions.

The SB informs the Board of Directors and the Board of Statutory Auditors on the status of the reports received.

The latter may provide recommendations, including whether or not disciplinary measures should be imposed.

It is strictly forbidden for any recipient of the Model to engage in direct or indirect retaliatory or discriminatory acts against the whistleblower for reasons directly or indirectly linked to the report. The SB has the duty to act by taking all necessary precautions to ensure that this principle is complied with, also ensuring the confidentiality of the identity of the whistleblower, without prejudice to legal obligations and the protection of the rights of the Company or of persons wrongly accused and/or in bad faith.

Information flows are divided into:

- **Periodic information flows** to be compiled and sent to the SB at a predetermined frequency (monthly, quarterly, half-yearly or yearly);
- **Event-driven information flows** to be compiled and sent to the SB upon the occurrence of certain events.

For details of formalised flows, both periodic and event-driven, please refer to the relevant paragraphs within the Chapters of the **Special Section**.

5.8.6 ADDITIONAL INFORMATION TO BE TRANSMITTED TO THE SUPERVISORY BODY

In addition to the formalised flows indicated in the above-mentioned Annex, all Recipients are required to transmit/report to the SB:

- internal reports from which responsibility for offences relevant for the purposes of the Decree or facts, events or omissions even only potentially referable to offences relevant for the purposes of the Decree emerge;
- visits, inspections and investigations undertaken by the competent bodies and their outcome;
- measures and/or information from law enforcement agencies or any other authority, indicating that investigations are being carried out, even against unknown persons, for offences under the Decree;
- requests for legal assistance made by members of the Board of Directors, executives and/or employees which are being investigated and/or prosecuted by the Judiciary for the offences provided for in the Decree;
- information about disciplinary proceedings (relating to the Model) and sanctions imposed or orders to close such proceedings and the reasons for the same;
- information on the development of activities pertaining to the risk areas identified by the Model and/or changes in the company organisation;
- information on security management and the status of implementation of planned actions;
- copies of the agenda of the meetings of the Board of Statutory Auditors and the Board of Directors;
- the organisational charts and the system of delegation of powers and signatures in force and any amendments thereto;
- certification of attendance at training courses by all Recipients of the Model.
- any information concerning the commission or attempt of unlawful conduct provided for in the Decree or which in any case is relevant for the purposes of the administrative liability of the Company;
- any information concerning violations of the behavioural and operational methods laid down in the Model, and more generally any act, fact or event or omission concerning any critical aspects that have emerged with regard to compliance with and proper implementation of the Model.
- news about changes in the internal structure of the Company.

All communications should be sent to the following e-mail address ODV@orthofix.it.

In order to fulfil its duties, the SB shall have free access to all relevant company documents and information.

5.9 Collection and storage of information

Any information, indication, flow, report provided for in the Model is kept by the Internal Member of the Supervisory Body in a special **computer and/or paper file**, in compliance with the confidentiality obligations provided for by Legislative Decree No. 196/2003 as amended, without prejudice to the fulfilment by the SB of the reporting obligations provided for by the Model.

6. Training, Communication and Updating

6.1 Training

In order to effectively implement the Model, the Compliance Function, in coordination with the SB and the Functions of the Company directly involved (Human Resources, *inter alia*), prepares, on the basis of the concrete needs identified by the Supervisory Body, an **annual training plan** for members of the Board of Directors, executives, employees and contractors working directly within the Company structure, as well as quasi-subordinate workers.

6.1.1 TRAINING CONTENT

In particular, the training activity will focus, inter alia, on the Model as a whole, the **Code of Ethics**, the **functioning of the Supervisory Body**, **information flows** to the latter and the **Disciplinary System**, the Company's **operating procedures** relevant to the Model, as well as **matters concerning the predicate offences** for which liability is applicable pursuant to Legislative Decree No. 231/01.

The training activity will be modulated, where necessary, in order to provide its users with the appropriate tools for full compliance with the provisions of the Decree in relation to the activities performed and the duties of the recipients of the training activity.

Training activities are **differentiated**, in terms of content and delivery methods, according to the qualification of the recipients, the risk level of the area in which they operate, and whether or not they have a representative function in the Company.

Training activities are managed by the Compliance Function, and by the other Functions of the Company responsible for training, in close cooperation with the SB.

6.1.2 ONBOARDING TRAINING

Upon hiring of **employees** and engaging **contractors** and **agents**, an information set shall be handed over to provide them the primary knowledge considered

essential to operate within the Company (see the following paragraphs).

6.1.3 CONTROL BY THE SUPERVISORY BODY

The **content of the courses** must be agreed in advance with the Supervisory Body, which, for this purpose, may and must indicate, within the scope of its activity, the subjects and topics that should be addressed and explored in depth or, in any case, to which it is necessary to draw the attention of the members of the corporate bodies and employees.

The Supervisory Body, in agreement with the Compliance Function and the other Functions of the Company responsible for training, ensures that the training programme is adequate and effectively implemented. Training initiatives may also take place remotely or through the use of computerised systems.

6.1.4 CONTINUING TRAINING AND UPDATES

Appropriate communication tools, where appropriate in addition to sending updates by e-mail, will be adopted to update Recipients on any changes

made to the Model, as well as any relevant procedural, regulatory or organisational changes

6.1.5 COMPULSORY NATURE OF TRAINING

Participation in the training is **compulsory** for all employees, contractors and all members of the Board of Directors who are not employees of the company and is recorded by the Compliance Function and by Human Resources (HR), which keeps track of it: failure to attend

training without justification will be appropriately sanctioned.

The Model is formally communicated in the manner described below.

6.2 Internal Communication

6.2.1 MEMBERS OF CORPORATE BODIES

Each member of the **corporate bodies** (directors and auditors) and each employee of the Company is required to:

- become aware of the contents of the Model;
- know the operating procedures for carrying out their activities;

- contribute actively, in relation to their role and responsibilities, to the effective implementation of the Model, reporting any shortcomings found in it.

6.2.2 EMPLOYEES

In order to guarantee an effective and rational communication activity, the Company promotes and facilitates the knowledge of the contents of the Model by the Employees, with different degrees of depth

depending on the degree of involvement in sensitive activities, as identified in the Special Part of the Model.

6.2.3 INFORMATION TOOLS

Information to the members of corporate bodies and employees on the content of the Model is ensured by means of:

- publication on the corporate intranet
- delivery or otherwise making available the Model and its annexes at the time

- of the hiring/engagement, also electronically;
- informative e-mails, also for the purpose of sending periodic updates of the Model.

6.2.4 TRAINING OWNERS

Responsibility for dissemination of the Model and its updates to employees lies with the head of the Human Resources (HR) Function, while dissemination of the Model to directors and auditors is the responsibility of the Compliance function. In particular, the above-mentioned functions shall send, through appropriate communication channels, depending on the circumstances (e-mail,

company training platforms, other) the documents to the recipients and receive through the same channel from each member the relevant acknowledgement of receipt. The Supervisory Body verifies that the competent functions ensure the proper dissemination of the Model and its updates.

6.2.5 CERTIFICATION

All members of corporate bodies (directors and auditors) and employees are required to fill-in a declaration in

which they, having acknowledged the Model, they undertake to comply with its provisions.

6.3 External Communication

6.3.1 EXTERNAL PARTIES

The activity of communicating the contents of the Model is also addressed to those Recipients of the Model who have relations of a contractual nature with the Company, but who are neither employees nor members of the corporate bodies.

The adoption of the Model, in fact, is also communicated and disseminated to External Parties who are not within the company's organisation, such as customers, suppliers, commercial partners (i.e. agents and distributors) and/or financial partners and consultants in general.

6.3.2 CONTRACTUAL CLAUSES FOR EXTERNAL PARTIES

The communication and formal commitment by the aforementioned external parties to the Company to comply with the principles of the Company's Code of Ethics and this Model are documented through the preparation of specific declarations or contractual clauses duly submitted to and accepted by the counterparty. More specifically, all relevant corporate functions must ensure that the contracts entered into include standardised clauses aimed at:

- compliance by the counterparties with the provisions of Legislative Decree 231/2001 and with the ethical and behavioural principles adopted by the Company;
- the inclusion of sanctioning mechanisms (termination of contract) in the event of violations of Legislative Decree 231/2001 and of the principles of ethics and conduct adopted by the Company.

Contracts with external contractors must contain an appropriate clause regulating the consequences

of their violation of the rules set out in the Decree as well as of the principles contained in the Model.

To this end, the Company Function that requested the service from the third party, or the Human Resources (HR) Function as far as contractors are concerned, upon signing the relevant contract shall deliver to the latter the relevant documents in terms of compliance, including - at the very least - a copy of the Code of Ethics and have a declaration filled in by which the third party, having acknowledged the content of the Code of Ethics and of the other documents referred to and/or delivered, undertakes to comply with their provisions.

Finally, on the occasion of the establishment of each new relationship, contracts with third parties who are Recipients of the Model must include specific clauses indicating clear responsibilities for non-compliance with this Model.

7. Disciplinary System

7.1 General Principles

Orthofix is aware that the provision of an adequate system of sanctions for violation of the rules contained in the Model is an essential condition for ensuring the effectiveness of the Model.

In this respect, in fact, Article 6(2)(e) and Article 7(4)(b) of Legislative Decree No. 231/2001 establish (with reference both to persons in top management and to subordinates) the need to set up "a disciplinary system capable of sanctioning non-compliance with the measures indicated in the model".

It represents an essential aspect for the effectiveness of the Model and consists of the establishment of an adequate system of sanctions for the violation of rules of conduct and, in general, of internal procedures (disciplinary offence).

The application of disciplinary sanctions is irrespective of the outcome of any criminal proceedings. Violation of the ethical rules of the Model and of the procedures contained therein and in its annexes, as well as of the company protocols and their updates, in fact, in themselves damage the relationship of trust in place with Orthofix and entail disciplinary action regardless of whether or not criminal proceedings are brought in cases where the violation constitutes an offence.

It should be noted that the offences that may give rise to the imposition of the sanctions described in the following paragraphs include:

- a) the adoption, by employees, managers, corporate bodies or third parties, of direct or indirect retaliatory or discriminatory actions against the person who made a report pursuant to paragraph 5.8 above, for reasons directly or indirectly linked to the report; and
- b) making, with wilful misconduct or gross negligence, a report pursuant to paragraph 5.8 above which resulted to be unfounded.

7.2 Criteria for the Application of Sanctions

In individual cases, the type and seriousness of specific sanctions will be applied based on the gravity of the misconduct and the following general criteria:

- a) subjective element of the conduct, depending on intent or negligence (negligence, imprudence, inexperience);
- b) significance of the obligations breached;
- c) relevance of the damage or degree of danger to the Company from the possible application of the sanctions provided for in Legislative Decree No. 231/2001;
- d) level of hierarchical and/or technical responsibility;
- e) aggravating or extenuating circumstances, with particular regard to previous work performance and disciplinary record;
- f) any sharing of responsibility with other workers who contributed to the misconduct.

Where a single action resulted in several infringements that are punishable by different penalties, the most serious penalty shall apply.

7.3 Scope and Relevant Conduct

7.3.1 COMPANY EMPLOYEES

Employees in non-executive positions

Conduct by employees in violation of the rules contained in this Model, its annexes and the procedures referred to therein are defined as disciplinary offences.

Without prejudice to the prior notification and the procedure prescribed by Article 7 of Law No. 300/1970 - for the purposes of which this "disciplinary system" is also made available in a place/way accessible to all -, the disciplinary sanctions set out below shall be applied against employees of the Company (non-executives) who engage in the following conduct:

- a) The adoption of direct or indirect retaliatory or discriminatory actions against the person who made a report pursuant to paragraph 5.8 above, for reasons directly or indirectly linked to the report;
- b) Making, with wilful misconduct or gross negligence, a report pursuant to paragraph 5.8 above which resulted to be unfounded
- c) failure to represent, or incomplete or untrue representation of the activities carried out with regard to the manner in which the documents relating to the procedures are documented, stored and controlled in such a way as to prevent the transparency and verifiability thereof;
- d) violation and/or circumvention of the control system, carried out through the removal, destruction or alteration of procedure documents
- e) or by preventing control or access to information and documentation by the persons in charge, including the Supervisory Body;
- e) non-compliance with the provisions contained in the Model, including those set out in the Code of Ethics;
- f) non-compliance with the provisions on signature powers and the system of delegated powers, especially in relation to related risks, including those related to corporate offences (especially the provisions on joint signature or powers), with regard to deeds and documents vis-à-vis the Public Administration and with regard to powers related to occupational health and safety;
- g) failure to supervise the conduct of personnel operating within their area of responsibility in order to verify their actions in the areas at risk of offences and, in any case, in the performance of activities related to operational processes at risk of offences;
- h) breach of the obligation to attend training courses (including on health and safety) provided by the Company, in the absence of appropriate justification;
- i) violation of internal company regulations and procedures requiring the adoption of safety and prevention measures;
- j) violation of the obligation to report to the SB in relation to any violation of the Model of which they have become aware.

Executive employees

Without prejudice to the prior notification and the procedure set forth by Article 7 of Law No. 300 of 20 May 1970 ("Workers' Statute") - for the purposes of which this "disciplinary system" is also posted in a place accessible to all -, the disciplinary sanctions set out below shall be applied against employees of the Company (executives) who engage in the conducts set out in points a) to j) of the preceding paragraph as well as the following additional specific conduct:

- k) engaging, in the performance of their duties, in conduct that does not conform to conduct reasonably expected of an executive, in relation to the position held and their degree of autonomy;
- l) breach of the obligation to report to the SB any anomalies or failures to comply with the Model, as well as any criticalities of which the manager has become aware relating to the performance of activities in the areas at risk by the persons in charge thereof.

Members of the Board of Directors of the Company and of the Board of Statutory Auditors

The sanctions set out below apply to members of the Board of Directors and the Board of Statutory Auditors who engage in the following conduct:

- a) non-compliance with the prescriptions contained in the Model or conduct that does not comply with the Model;
- b) breach of the duty of supervision and control over subordinates (in relation to members of the Board of Directors);
- c) delay in taking measures following reports of violations of the Model received by the SB.

7.3.2 THIRD PARTIES

The measures set out below apply to third parties, meaning all persons who, for any reason, have relations with the Company and which are not employees and members of the Board of Directors (by way of example, contractors, external consultants, commercial and/or financial partners, suppliers), who

engage in the following conduct:

- a) non-compliance with the prescriptions contained in the Code of Ethics and in the provisions of the Model applicable to them;
- b) commission of relevant offences pursuant to Legislative Decree 231/2001.

7.4 Procedure for Assessing Violations and Applying Sanctions

Upon receiving notice of any breach of the Model that does not involve the Managing Director, the Supervisory Body shall inform the latter, who shall be required to initiate the relevant **disciplinary proceedings**, with the technical support of the competent corporate structures.

In the event that, following the checks and assessments carried out, a violation of the Model is ascertained, the Board of Directors or the Human Resources (HR) Function, in compliance with the disciplinary regulations and in accordance also with the guarantees provided for by the law and collective bargaining agreements, shall impose on the author(s) of the violation(s) the sanctions provided for in the applicable national collective bargaining agreements, after informing the Board of Statutory Auditors.

Where violations of the Model are attributable to the **Managing Director**, the Supervisory Body shall inform the Board of Directors and the Board of Statutory Auditors for the adoption of the appropriate measures.

In the event of a breach of the Model by one or more of the **Members of the Company's Board of Directors**, the SB shall inform the Board of Directors and the Board of Statutory Auditors without delay. The recipients of the information from the Supervisory Body may, in accordance with the provisions of the articles of association, take the appropriate measures, including, for instance, convening the Shareholders' Meeting in order to adopt the most appropriate measures provided for by law.

If the breach is committed by the Board of **Directors as a whole** (e.g. by means of a resolution of the Board of Directors itself), the SB shall promptly report it to the Board of Statutory Auditors, which may take the appropriate measures, including, for instance, convening the Shareholders' Meeting, in order to adopt the most appropriate measures provided for by law.

In the event that one or more of the Directors, alleged to be perpetrators of the offence from which the administrative liability of the Company derives, are **indicted**, the Chairman of the Board of Directors of Orthofix or the Board of Statutory Auditors shall proceed to convene the Shareholders' Meeting to resolve on the removal from office.

In order to enable the monitoring of the application of disciplinary sanctions to employees, the Human Resources (HR) Function informs the Supervisory Body of the application of such sanctions.

7.5 Sanctions

7.5.1 SANCTIONS AGAINST EMPLOYEES

Disciplinary sanctions are applicable against employees (including executives) who have engaged in the conducts described above in violation of the rules and principles set out in this Model, in compliance with the provisions of:

- Article 7 of the Law of 30 May 1970 - Workers' Statute and its additions and amendments;
- the applicable articles of the Italian Civil Code (e.g. Article 2106 of the Italian Civil Code);
- National Collective Labour Agreement for Metalworkers of Small and Medium Enterprises (hereinafter referred to in short as "NCLA SME Metalworkers");
- any other special regulations applicable.

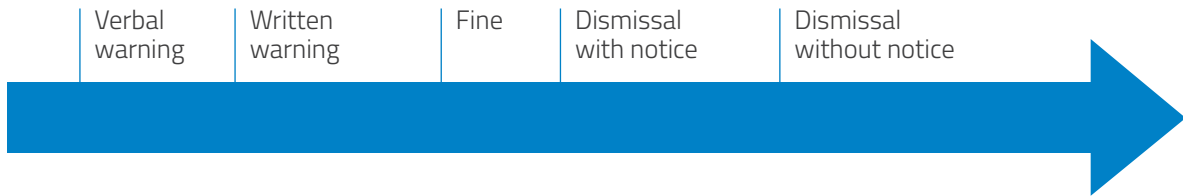
Violation by employees of the rules of this Model, of the annexes thereto and of the procedures referred to therein may give rise, depending on the seriousness of the violation itself, to the following measures, which are established in application of the principles of proportionality and of the criteria of correlation between offence and sanction and, in any case, in compliance with the form and modalities provided for by the legislation in force:

- **verbal warning**: this sanction will be imposed in cases of less serious wrongful conduct or minor non-compliance with the Model and the employee's obligations that has not caused consequences of external relevance;
- **written warning**: this sanction will be imposed in cases of:
 - a) repeated violations that led to the verbal warning sanction, provided that it was imposed in the two years preceding the repetition;
 - b) minor non-compliance with the Model and the obligations incumbent on the employee himself which, however, have produced consequences with external relevance;
- **fine not exceeding three hours' pay**. This sanction will be imposed in cases of
 - a) repeated violations that led to the written warning sanction,
 - b) non-serious failure to comply with the Model and the obligations placed on the employee;
- suspension from work and pay up to a maximum of three days: this sanction will be imposed in cases of
 - a) repeated violations that led to the fine sanction, provided that it was imposed in the two years preceding the repetition;
 - b) serious failure to comply with the Model and the obligations placed on the employee;
 - c) serious procedural violations capable of exposing the Company to liability vis-à-vis third parties;
- dismissal with notice: this sanction will be imposed in cases of
 - a) repeated violations that led to the suspension sanction, provided that it was imposed in the two years preceding the repetition;
 - b) serious breach of the Model and of the obligations incumbent on the employee himself in relation to proceedings in which the Public Administration is a party, serious failure to comply with a procedure aimed at preventing conduct constituting corporate offences;
- dismissal without notice: this sanction will be imposed in cases of wilful violations of the Model and of the employee's obligations, such as, by way of example
 - a) wilful violation of externally relevant procedures and/or fraudulent circumvention carried out through behaviour unequivocally aimed at committing an offence relevant under Legislative Decree 231/2001, such as to break the fiduciary relationship with the employer
 - b) wilful breach and/or circumvention of the internal control system by removing, destroying or altering the documentation of a procedure or by impeding the auditing of or access to the information or documentation by the persons in charge, including the Supervisory Body,
 - c) failure to document, or incomplete or untrue documentation of the activities carried out with regard to the manner in which the documents relating to the procedures are documented and stored, wilfully aimed at preventing the transparency and verifiability thereof.

The Human Resources (HR) Function is responsible for managing the formal and communication process relating to the imposition of sanctions under this Model.

The Human Resources (HR) Function reports to the Supervisory Body on the application of disciplinary sanctions issued. The Supervisory Body monitors the application of disciplinary sanctions.

Sanctions against Employees in order of severity:



7.5.2 MEASURES AGAINST THE BOARD OF DIRECTORS AND ITS MEMBERS AND AGAINST THE BOARD OF STATUTORY AUDITORS AND ITS MEMBERS

The following sanctions are applicable to members of the Board of Directors and the Board of Statutory Auditors who have engaged in the conduct referred to in the preceding paragraphs in breach of the rules and principles set out in this Model:

- **written warning** in the event of minor violations of the Model or of the obligations of supervision and control over subordinates (in relation to members of the Board of Directors) or of minor delays in taking measures following reports of violations of the Model received by the SB;
- in the case of members of the Company's Board of Directors, **revocation of** the delegated power and/or removal from office in the event of serious violations of the Model or of the obligations of supervision and control over subordinates or of serious delay in taking measures following reports of violations of the Model received by the SB;
- in the case of members of the Board of Statutory Auditors, **removal** from office in the event of serious

violations of the Model or of serious delay in taking measures following reports of violations of the Model received by the SB.

Violations committed by members of the Board of Directors or the Board of Statutory Auditors may also give rise to **liability action**, if the conditions provided for by law are met.

Violations of the Model by members of the Board of Directors or the Board of Statutory Auditors must be reported to the SB without delay by the person who detects them. If the report is not manifestly groundless, the SB shall inform the Board of Directors as a whole, in the person of its Chairman (if the report does not concern them) and the Board of Statutory Auditors.

Once the necessary investigations have been carried out, the Board of Directors takes the measures it deems appropriate.

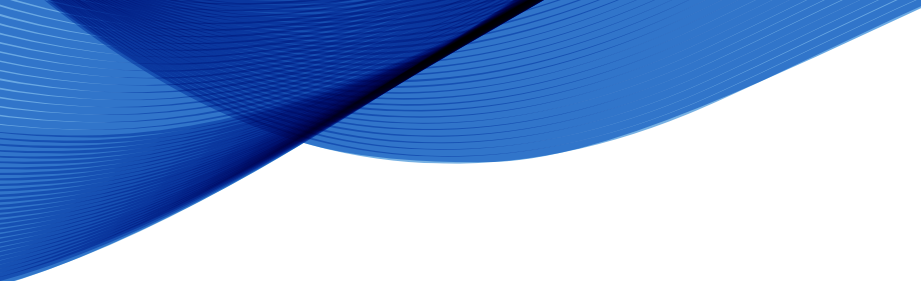
7.5.3 MEASURES AGAINST THIRD PARTIES

The conduct referred to in the preceding paragraphs carried out by third parties as identified above shall constitute a **breach of contractual obligation** with the Company and may give rise to **termination of** the contractual relationship as provided for in the individual agreements.

The breach must be reported without delay to the Managing Director of the Company and to the SB by the person detecting it.

If the report is well-founded, the Managing Director shall give prompt instructions for the immediate termination of the contract, keeping the SB informed.

Any conduct by contractors, including occasional contractors, consultants, trainees, agents of Orthofix or by commercial partners in conflict with this Model may result, in accordance with the provisions of the specific contractual clauses (see chapter 6 above), in the immediate termination of the relationship, without prejudice to any claim for **compensation** for any damage caused to the Company, as well as the prohibition of new contractual relationships with the Company, unless for derogations which shall be justified and communicated by the Managing Director to the SB.



ORTHOFIX Srl
Via Delle Nazioni 9,
37012 Bussolengo
(Verona), Italy
Telephone: +39 045 6719000
Fax: +39 045 6719380
www.orthofix.com



orthofix.com
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