ORTHOFIX®

SUPPLIER QUALITY MANUAL

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Introduction

Purpose and Scope

The purpose of this Supplier Quality Manual (the Supplier Manual) is to communicate the Supplier expectations to all new and existing Suppliers. These expectations should be fully understood prior to a Supplier entering into a relationship with Orthofix Medical Inc., or any of its subsidiaries (collectively herein referred to as Orthofix), and prior to quoting products or services to the company.

This Supplier Manual applies to all Suppliers where Orthofix is established as the manufacturer on record and includes finished medical devices, raw materials, components, Original Equipment Manufacturers (OEM), packaging and service suppliers associated with the product and service.

Suppliers have a direct impact to Orthofix delivering high-quality products to our customers. Therefore, it is important to fully understand expectations, identify gaps and track progress to gap resolution. Orthofix strives to establish long-term partnerships with Suppliers and develop the relationship on an ongoing basis.

Quality requirements and expectations may take the form of an agreement or specification. The expectations and guidance within this Supplier Manual are provided as a supplement, not as a replacement for or alteration of the terms or conditions of pre-established agreements, engineering drawings or specifications.

If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

- Agreements (Quality, Supply, etc.)
- Specification requirements/engineering drawings
- Orthofix Purchase Orders
- Supplier Manual

We recognize that Orthofix has a wide variety of Suppliers and technologies; the expectations stated in this manual may apply in different ways, depending on the product or service supplied.

Orthofix Mission and Quality Policy

Orthofix Mission

Orthofix is a global medical device company with a spine and orthopedics focus. Our mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patient mobility.

Quality Policy

Orthofix is dedicated to improving patient's lives through high-quality products, procedures and services. We are committed to executing an effective quality management system that meets or exceeds global regulatory requirements.

Orthofix Business Lines and Products

Our team members are dedicated to developing, manufacturing, marketing and distributing orthopedic and spine products and regenerative tissue forms that empower surgeons to meet the needs of their patients every day.

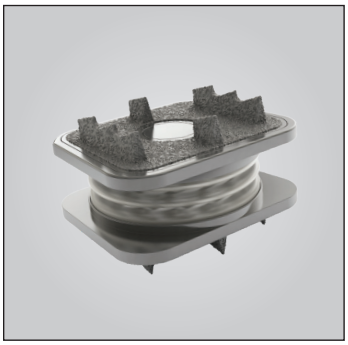
Orthofix is proud to collaborate with leading clinical organizations, such as MTF Biologics and the Texas Scottish Rite Hospital for Children. Many of our innovative products are the result of working closely with leading physicians and healthcare organizations.

At Orthofix we believe that each of us can make a difference in the life of a patient through our innovative medical devices and biologics. We are passionate about improving patients' lives and driven by our culture of integrity. It's what makes each one of us, from the CEO to our fantastic customer service team, want to come to work each day.

Headquartered in Lewisville, Texas, we have two reporting segments: Global Spine and Global Orthopedics. Our spine and orthopedic products are globally distributed via our sales representatives and distributors.

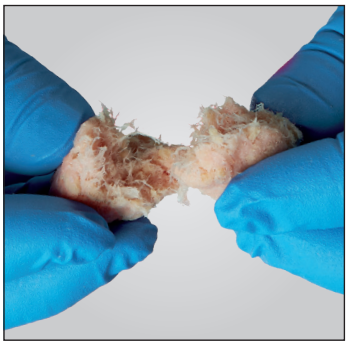
Orthofix Spine Solutions

We provide reconstructive and regenerative solutions that aim to restore the quality of life for patients with various spinal and bone related conditions. Our innovative solutions uniquely incorporate different treatment modalities (mechanical, biological, and electromagnetic) to achieve desired clinical outcomes, such as helping patients maintain their range of motion or achieve successful spinal fusions.



Motion Preservation

BioStim

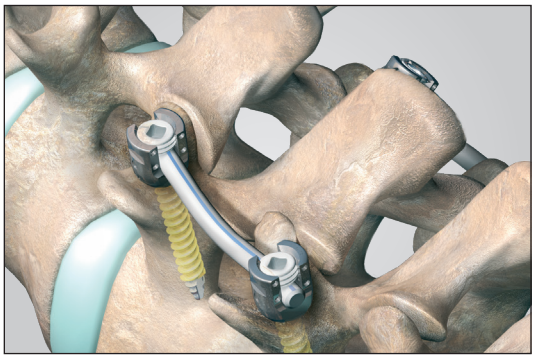


Biologics

Spine Fixation

Spine Fixation

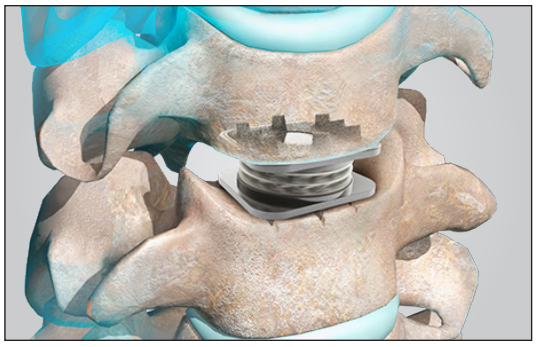
We are committed to helping restore quality of life for our patients through advanced interbody and fixation solutions that aid surgeons in repairing spinal alignment, improving disc height, providing nerve decompression and correcting instabilities. Our spine fixation products are used globally in a variety of spine procedures involving deformity correction, minimally invasive approaches, sacroiliac joints, degenerative disc disease, trauma and tumors.



Firebird™ NXG

Motion Preservation

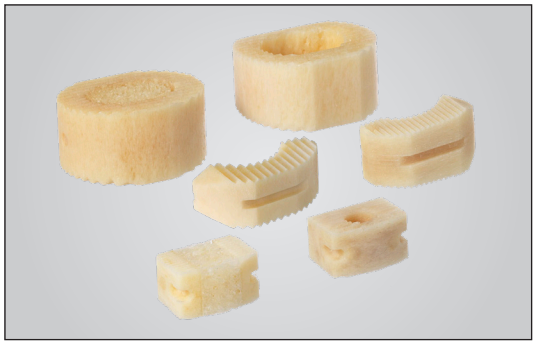
Our M6 artificial discs are the natural choice for helping preserve motion in patients undergoing cervical or lumbar disc replacement. Designed to restore physiologic motion to the spine, the M6 discs preserve motion by restoring biomechanical function at the treated level after native disc removal and potentially reduces subsequent degeneration of adjacent vertebral segments. The M6 devices mimic the anatomic structure of a natural disc by incorporating an artificial visco-elastic nucleus and fiber annulus into their design. Like a natural disc, this unique construct allows for shock absorption at the implanted level, as well as provides a controlled range of motion when the spine transitions in its combined complex movements.



M6-C™ Artificial Cervical Disc

Biologics

Our biologic solutions play an important role in a number of surgical applications. These solutions include allografts with viable cells, structural allografts, synthetic bone grafts, and amniotic membranes. By supplying the key elements needed for bone healing coupled with its enhanced handling properties, our leading allograft solutions, Trinity Evolution™ and the Trinity ELITE™ allograft with viable cells, have been implanted in over 200,000 spine and orthopedic procedures.



AlloQuent™ Structural Allografts

Bone Growth Therapy

With over 30 years of healing patients, our bone growth therapy devices are the number one prescribed bone growth stimulators in the U.S. These devices provide patients with safe, nonsurgical treatment options for promoting spinal fusion and healing nonunion fractures. Using Orthofix's pulsed electromagnetic field (PEMF) technology, the devices generate a uniform, low-level electrical field that helps activate and augment the body's natural healing process to enhance bone fusion.

CervicalStim™

SpinalStim™

PhysioStim™

Orthofix Orthopedics Solutions

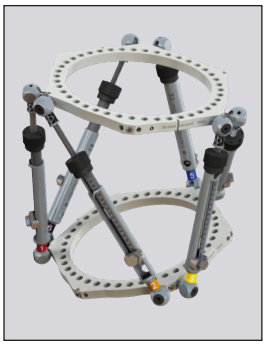
Orthofix offers innovative and minimally invasive orthopedics solutions to help surgeons improve their patient's quality of life. Designed to address the lifelong bone and joint health needs of patients of all ages, our orthopedics products help patients achieve a more active and mobile lifestyle when compared to other surgical solutions. Our well-rounded product lines offer comprehensive solutions for pediatrics, limb reconstruction, fracture management, and foot and ankle specialties.

Pediatrics and Limb Reconstruction

Orthofix offers solutions at the forefront of limb reconstruction, whether post-traumatic, correction of deformity, limb lengthening or pediatric surgery. A comprehensive portfolio of adult limb reconstruction solutions combines both products and digital services addressing the needs of today's patient, surgeon and care team.

With a long history of cutting-edge pediatric solutions, we bring all of our pediatric expertise and products together under the JuniOrtho™ banner. We help surgeons give children with bone traumas and deformities the best opportunity to achieve their potential with the JuniOrtho range of orthopedic products and resources. To learn more about pediatric solutions, visit JuniOrtho.club.

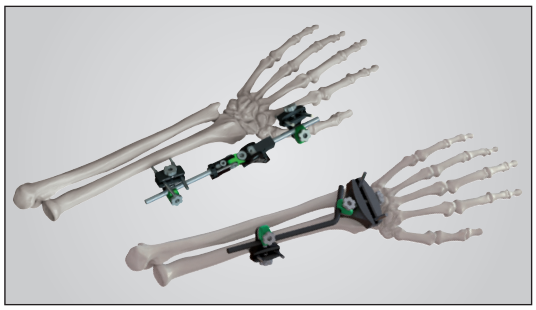
Eight-Plate System™



TL-HEX™

Fracture Management

Orthofix trauma solutions comprise a wide range of devices designed for specific anatomical areas. The philosophy underlying these devices is to provide adequate stability and allow for early functional recovery thereby improving patients' quality of life. Our continuous effort is to offer devices that enable a simple, standardized approach for reproducible results.



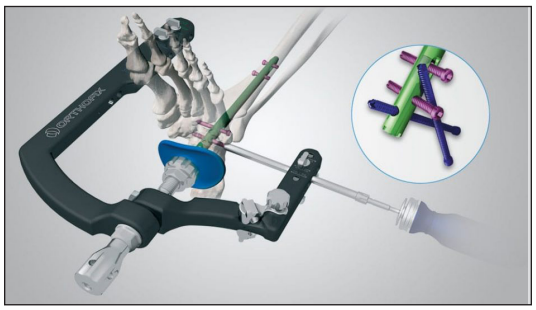
Galaxy™ Fixation system

Foot and Ankle

Solutions in our Foot and Ankle portfolio include products that can treat a wide range of deformities and traumatic injuries. Extremity solutions are available for deformities present at birth or post-trauma, as well as for patients needing limb lengthening.

Our products are used to treat conditions such as Charcot foot and ankle, calcaneal fractures, ankle fusions and other small bone fusions.

For more information about Orthofix products and the patients we serve, please visit Orthofix.com.



Ankle Hindfoot Nailing™ (AHN) system

General Compliance

Ethics and Compliance

Orthofix strives to conduct business honestly and ethically and in compliance with all laws and regulations applicable to our business. We expect our Suppliers to do the same. Working together, we can achieve great success by doing the right thing.

We expect our Suppliers and business partners to communicate these expectations throughout their supply chain by adopting efficient management systems, policies, procedures and training to uphold the standards and expectations set forth in this Supplier Code within their own business operations.

We require our Suppliers to abide by all applicable national, state and local laws/regulations in the markets where they operate; however, where local laws or standards differ from this Supplier Manual, we expect our Suppliers to comply with the more stringent standards and principles.

Conflicts of Interest

A conflict of interest is a situation in which a person or organization has conflicting interests or responsibilities, financial or otherwise, and serving one interest could have an adverse impact on those other interests or responsibilities. Suppliers are expected to disclose to Orthofix any situation that may present a conflict of interest with respect to Orthofix. For that reason, Suppliers must inform Orthofix if an employee of any Supplier, or their family member, has a relationship with an Orthofix employee who can make decisions that will affect such Supplier's business, or if any Orthofix employee, or their family member, may have an interest of any kind in such Supplier's business or any kind of economic ties with such Supplier. All disclosures will be made to Orthofix Ethics and Compliance office at **Compliance@Orthofix.com** or use the Company's EthicsPoint reporting service at **Orthofix.EthicsPoint.com** or call toll-free 1-855-603-6985.

Gifts, Meals and Entertainment

Suppliers, vendors and others who do business with us are vital to our Company's success. To keep our relationships with them honest and objective, we avoid conflicts of interest. Orthofix employees are prohibited from accepting anything more than modest gifts and meals from suppliers. Ordinary business meals and small tokens of appreciation such as gift baskets at holiday time generally are fine, but suppliers should not offer Orthofix employees travel, frequent meals or expensive gifts. Gifts of cash or cash equivalents, such as gift cards, are never allowed.

Business and Financial Records

Supplier must keep accurate records of all matters related to the Supplier's business with Orthofix. This includes the proper recording of all expenses and payments. If Orthofix is being charged for a Supplier employee's time, time records must be complete and accurate. Suppliers should not delay sending an invoice or otherwise enable the shifting of an expense to a different accounting period.

Bribery

Orthofix takes a strong stance against corruption and bribery consistent with applicable anti-bribery and anti-corruption laws. We expect the same from our business partners. We strictly prohibit bribes, fraudulent conduct, kickbacks, illegal payments and any other offer of items of value that may inappropriately influence or secure an improper advantage with a government official, healthcare professional or customer.

Press/Publicity

Suppliers shall not speak to the press on our behalf or publicly disclose our name, logo, products, parts, designs, relationships, or any other nonpublic information without our prior written authorization.

Insider Trading

Suppliers shall not buy or sell our securities or another company's securities when in possession of information about us or another company that is not available to the investing public and that could influence an investor's decision to buy or sell such security.

Fair Competition and Practices

Suppliers shall compete for all business opportunities fairly, ethically, legally, and in compliance with all antitrust and fair competition laws regulating competition and trade in each country where they conduct business. Our Suppliers shall not engage in collusive bidding, price fixing, price discrimination, or other unfair trade practices in violation of antitrust laws.

Reporting Potential Misconduct

Suppliers who believe that an employee of Orthofix, or anyone acting on behalf of Orthofix, has engaged in illegal or otherwise improper conduct, should report the matter promptly. The Supplier may contact Orthofix Ethics and Compliance Office at **Compliance@Orthofix.com**, or use the Company's EthicsPoint reporting service at **www.Orthofix.EthicsPoint.com**, or call toll-free 1-855-603-6985. A Supplier's relationship with Orthofix will not be affected by an honest report of potential misconduct.

General Business

Our Suppliers shall conduct their business interactions and activities in an ethical and lawful manner and shall, without limitation:

Marketing and Sales

Represent their products and services accurately and comply with applicable regulatory and legal requirements governing the marketing and sale of their products and services.

Fair Dealing

Deal fairly with customers, suppliers, competitors, independent auditors, employees, and any regulatory or government officials and not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other unfair dealing or practice.

Anti-Counterfeiting

Develop, implement, and maintain methods and processes appropriate to their products and services to minimize the risk of introducing counterfeit parts and materials into our products.

Human Rights, Labor and Employment

Our Suppliers must honor human rights and equal opportunity in the workplace and shall, without limitation:

Nondiscrimination

Maintain human dignity and respect and a workplace that is free from discrimination and harassment based on race, color, sex, age, disability, religion, sexual orientation, gender identity or expression, pregnancy, ancestry, marital status, national origin, citizenship status, disability, genetic information, veteran status, service in state or U.S. military service, AIDS or HIV status, or any other characteristic protected by applicable federal, state or local laws.

Forced, Involuntary Labor, and Human Trafficking

Not support, promote or use compulsory labor, slavery, forced or involuntary labor, or human trafficking of any kind.

As a Suppliers of Orthofix, Suppliers must comply with the requirements of the California Transparency in Supply Chains Act (the "CTSC Act").

Our Suppliers shall:

- Engage in verification activities to identify, assess and manage the risks of human trafficking in their product supply chain.
- Confirm whether they audit their suppliers in evaluating compliance with their standards for trafficking and slavery in their supply chains, and whether such audits are independent and unannounced.
- Certify that materials incorporated into the product comply with the laws regarding slavery and human trafficking of the country or countries in which they are doing business.
- Maintain internal accountability standards and procedures for employees or contractors failing to meet their standards regarding slavery and trafficking.
- Provide their employees and management who have a direct responsibility for supply chain management with training on human trafficking and slavery, particularly with respect to mitigating risks within the supply chains of products.

In order to verify Suppliers' compliance, Orthofix may, itself or through third parties, verify how Suppliers address risks of human trafficking and slavery and conduct audits to evaluate compliance with Orthofix standards, and Orthofix may require Suppliers to certify that materials incorporated into their products supplied to Orthofix comply with the laws regarding slavery and human trafficking of the countries in which we do business. If Supplier refuses to provide any requested documentation or submit to an audit, Supplier shall be in material breach of any contract between Supplier and Orthofix.

Safe Working Environment

Not engage in physical discipline or abuse or the threat thereof or other forms of physical coercion or harassment.

Will employ or use only workers who have a legal right to work in the jurisdiction in which the supplier intends to hire such employees. Our Suppliers shall review appropriate and relevant documentation and ensure the legal status of prospective employees prior to hiring such employee.

Immigration Laws and Proper Documentation

Will employ or use only workers who have a legal right to work in the jurisdiction in which the Supplier intends to hire such employees. Our Suppliers shall review appropriate and relevant documentation and ensure the legal status of prospective employees prior to hiring such employee.

Wages and Benefits

Comply with all applicable wage and hour laws and regulations, including those relating to minimum wages, overtime hours, piece rates, and proper classification, and provide legally required benefits.

Working Hours

Not exceed maximum hours of work prescribed by law and will ensure that overtime is paid in accordance with local laws and regulations.

Freedom of Association

Comply with all laws regarding the rights of employees to associate or not associate with any legally constituted group (e.g. a union or works council).

Health, Safety, and Environment

Our Suppliers must ensure the health and safety of their workplace and of the environment and shall, without limitation:

Environment

Comply with all applicable laws, regulations, standards, ordinances, rules, permits, license approvals and orders regarding the environment and the use of restricted substances. Our Suppliers shall obtain, maintain and keep current all required environmental permits, licenses, registrations and approvals as well as any operational reporting requirements as identified in the laws, regulations, standards, ordinances, etc. of the country in which the facility is located. See section 2.7 for additional information on this topic.

Hazardous and Restricted Substances

Comply with all applicable environmental laws and regulations regarding waste, hazardous or toxic materials and identify and disclose to us all chemicals in products that are regulated by governments and other authorities in the applicable countries/regions where they are being used. Suppliers shall safely manage hazardous materials and waste from point of entry to the point of final disposal.

Work Environment

Provide a safe and healthy working environment and comply with all applicable health and safety laws, including, where appropriate, addressing occupational injury and illness, emergency preparedness, and occupational safety.

Facility Security

Maintain adequate security at Supplier facilities at all times. Additionally, Suppliers and their Representatives must comply with our security procedures when at our facilities.

Intellectual Property and Data

Our Suppliers must protect our intellectual property, shared data, and information systems and shall, without limitation:

Intellectual Property

Respect our intellectual property ownership rights and the rights of others, observe and respect all patents, trademarks, and copyrights, and comply with all requirements and terms of their use. Our Suppliers will not, without our express consent, disclose to others nor use for their own purposes or the purpose of others any of our trade secrets, confidential and proprietary information, knowledge, designs, data, skill, or any other information considered by us as "confidential." Our Suppliers will not provide us with the confidential information of third parties, unless consent has been obtained from such third parties.

Data Privacy

Process all personal information fairly and lawfully and in accordance with all data protection and privacy laws applicable to such personal information. Our Suppliers shall adopt adequate technical and organizational measures necessary to secure personal information and to prevent unauthorized access, alteration or loss.

Information Systems Security and Use

Comply with our requirements and procedures for maintaining passwords, confidentiality and security as a condition of providing us with products or services or receiving access to our internal systems, network and facilities. Our provided technology shall only be used for authorized business-related purposes. Our Suppliers and their Representatives shall not knowingly download, view or send materials of a discriminatory, harassing, threatening, sexual, pornographic, racist, sexist, defamatory or otherwise offensive nature.

Non-Disclosure Agreements

Suppliers may be asked to sign a non-disclosure agreement, depending on the level of technology or information disclosed during the course of business. An Orthofix standard form has been created for this purpose.

Information provided to Suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or advertise the existence of its agreement with Orthofix, divulge its terms and conditions or any relationship with Orthofix other than with prior written agreement of Orthofix. Suppliers agree not to display or use the Orthofix logo, trade secrets, trademark, or product(s) unless authorized by Orthofix.

Environmental and Social Responsibility Obligations

Together, Orthofix and its suppliers are required to comply with all relevant environmental and medical device regulations relating to materials within products. This may be achieved by restricting, labeling, or controlling materials and/or by implementing collection and waste reduction programs. Failure to comply with geography-specific laws may prohibit sales of a device in that geography. Regulations that restrict the use of certain materials include, but are not limited to, the EU Medical Device Directive (Regulation), the RoHS Directive, the REACH Regulation, and rules concerning materials safety and materials of animal origin. Therefore, suppliers shall have knowledge of, and inform Orthofix of, restricted and regulated materials that are used to manufacture, process, or package products for Orthofix. It is expected that all local government regulations are met.

Environmental Compliance

Products and services supplied to Orthofix are expected to meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of the following or chemical composition of products. Any suspicions that products supplied to Orthofix are not compliant, are expected to be communicated to the appropriate buyer or supply chain representative immediately.

- Battery and Accumulator Directive 2006/66/EC
- Packaging Directives 94/62/EC, 2004/12/EC, COM Decision 97/129/EC
- REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC
- RoHS (Restriction of Hazardous Substances) EU 2003/95/EC and China
- WEEE (Waste Electrical and Electronic Equipment) Directive 2001/96/EC
- Medical Device Directive 93/42/EEC, amended by the Directive 2007/47/EC
- Medical Device Regulation EU 2017/745 of the European Parliament

Conflict Minerals

Orthofix expects its Suppliers to comply with the U.S. Securities and Exchange Commission (SEC) rules for reporting and disclosure requirements related to conflict minerals as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act"). Orthofix supports the goals and objectives of Section 1502 of the Dodd-Frank Act that requires public companies to determine the sourcing of tin, tungsten, tantalum, and gold used in their products and to file an annual report disclosing any such use. As part of our commitment to responsible sourcing and human welfare, our Suppliers are expected to adopt a conflict minerals policy. Suppliers are expected to provide pertinent information regarding conflict

minerals to allow Orthofix to comply with section 1502 of the Dodd-Frank Act of 2010, even if they are not subject to the regulation themselves, by providing periodic certifications to Orthofix concerning the origin of tin, tungsten, tantalum, and gold included in products and components supplied to the Orthofix. Orthofix will consider conflict minerals status as an input to the supplier selection process.

C-TPAT

Orthofix expects Suppliers to obtain certification with Customs-Trade Partnership Against Terrorism (C-TPAT):

- Obtain certification under the U.S. C-TPAT program and provide evidence of such certification to Orthofix; or
- Demonstrate to Orthofix that it meets the criteria for such certification and has policies and procedures in place that meet C-TPAT requirements.

The U.S. Customs-Trade Partnership Against Terrorism seeks to safeguard the world's vibrant trade industry from terrorists, maintaining the economic health of the U.S. and its neighbors. The partnership develops and adopts measures that add security but do not have a chilling effect on trade. Further information can be found at www.cbp.gov.

Import Compliance

As business becomes increasingly globalized, additional documentation and processes are required. Suppliers who ship product from outside the U.S. to an Orthofix facility within the U.S. need to be aware of the following:

Orthofix requires that, unless exempted by law, every article of foreign origin, or its container imported into the U.S. be marked in a conspicuous place as legibly and permanently as possible to indicate the English name of the country of origin to an ultimate purchaser in the U.S.

A commercial invoice signed by the seller, shipper or associated agent is required for Customs entry and is expected to be prepared in accordance with 19 CFR 141.86 of the customs regulations. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased review by import specialists or penalties against the importer.

Wood packaging material is closely regulated as it pertains to importation of goods into the U.S. The standard calls for wood packaging material to be either heat-treated or fumigated with methyl bromide, in accordance with the Guidelines for Liquidated Damages and Penalties on Non-Compliant Wood Packaging Materials (WPM) (refer to International Plant Protection Convention (IPPC)), and marked with an approved international mark certifying treatment.

Declaration of Raw Materials Used

Suppliers of components and finished devices are expected to have information about the composition (e.g. Trade or Chemical name, Color, Grade, etc.) on hand and make such information available to Orthofix upon request. This detailed information, declaring the raw materials used to manufacture a product is required to fulfill regulatory body requirements for approval or use. If colorants are used, additional details (e.g. Color Description, Trade Name, etc.) for each ingredient or pigment used in the colorant formulation are expected to be known by the Supplier and made available as needed. Suppliers are expected to provide disclosure on 100% of the material composition. Due to the ever-changing landscape of materials regulations, obtaining full material composition from Suppliers will allow Orthofix to automatically evaluate materials against new regulations and reduce the need for future declaration requests.

Orthofix prohibits the use of metals sourced from China to be used in the manufacturing of its products. Orthofix further prohibits the use of any recycled raw material in the manufacturing of its products.

Latex

Suppliers shall ensure Orthofix products are not made with natural rubber. In other words, Suppliers must ensure products:
are not made with natural rubber or natural rubber latex in either the product ingredients or the packaging; and
do not come in contact with any natural rubber products throughout the manufacturing process.

General Requirements

Open Communication and Feedback

Fundamental to the partnership between Orthofix and its Suppliers is a willingness to collaborate and communicate effectively at all levels. Open and direct access to personnel and facilities is expected. Information exchanged shall include the following areas:

- Quality Data – traceability and other processing data available to Orthofix when addressing quality or compliance concerns.
- Strategic Planning – executive level communication to ensure alignment of vision, strategy, and execution, including strategies regarding supplier locations, strategic technology investments and capacity investments.
- Business Initiatives – planning to meet material costs, supply agreement, forecast, purchasing and logistics requirements.
- New Product Development (NPD) – product roadmap, technology integration and next generation product research and development.
- Open access to Orthofix for process documentation such as process flows, control plans, and material controls to allow for accurate assessment of process risk.

Quality and Regulations

Suppliers are responsible for ensuring that products or services meet established Orthofix specifications and quality requirements. Audits, approvals or verification by Orthofix of the Supplier's facility, quality system, process controls, acceptance activities, etc., does not absolve the Supplier of the responsibility to provide acceptable products or services, nor will it preclude the subsequent rejection of unacceptable product. Suppliers directly share in the responsibility to ensure the highest degree of care is taken to meet or exceed all specified quality and reliability requirements. Orthofix expects:

- Finished device suppliers to be registered with the U.S. Food and Drug Administration (FDA).
- Certification to a ISO 9001 or ISO 13485; not required for service only supplier.
- Suppliers provide data to demonstrate compliance to applicable external regulations and standards.
- Materials, components, assemblies, services and finished medical devices supplied to Orthofix meet or exceed all quality and product specification requirements.
- Suppliers have a compliant quality system that meets Orthofix Supplier Assessment Requirements.
- Suppliers review and sign a Quality Agreement/Addendum (SQA) when required.
- Suppliers maintain a manufacturing environment with appropriate temperature, humidity or other environmental controls. Systems shall be in place to prevent damage, deterioration, contamination or other adverse effects from occurring during the manufacture or delivery of products.
- Suppliers have a documented process for line clearance and process/product changeovers to prevent mix-ups, to prevent use of incorrect materials/components, and to ensure traceability.
- Supplier maintains a Device History Record (DHR) for the manufacturing and quality documentation of each lot/batch produced.
- Suppliers support regulatory audits and unannounced audits by notified bodies or by Orthofix.
- Supplier shall use best practices in performing root cause analyses, in a prompt fashion, to resolve issues related to its products.
- Supplier shall identify to Orthofix the Quality Management Representative within the Supplier's organization, who is responsible for the implementation and maintenance of the Supplier's Quality Management System such as defined by ISO 9001 and/or the ISO 13485 series of standards.
- Supplier support for projects, continuous improvements, and necessary registration for Orthofix product: i.e. FDA device registration through the FURLS process per part 21 CFR part 807 and other Third Party Registration.

Manufacturing Controls and Technology

Orthofix seeks to partner with suppliers with demonstrated technology leadership and a commitment to investing in continued technology development. Orthofix expects all Suppliers to:

- Implement formal, management-sponsored continuous improvement initiatives. Examples include Six Sigma, Lean, or Total Quality Management.
- Implement Statistical Process Controls (SPC) for all critical input and output process variables.
- Perform PFMEAs (Process Failure Mode Effect Analysis) during manufacturing process development to identify key or high risk characteristics. As a result of the PFMEA activity, a Control Plan shall be developed to control these characteristics. Reference AIAG industry standards for guidance on PFMEA and Control Plans. The PFMEAs and Control Plans shall be living documents and should be reviewed /updated whenever there is a product or process change.
- Have a master validation plan established to monitor and control process validations.
- Have documented evidence of equipment qualifications.
- Achieve process capabilities for all critical input and output process variables.
- Have a fully validated cleaning process for product that contains results for the following tests:
  - Visual inspection process for cleaned products
  - Cytotoxicity
  - Gravimetric Analysis to show reduction of manufacturing materials evidence
  - Total Organic Carbons for final rinse, where appropriate
  - Bioburden – only when the product supplied will be sterile packaged or when required by Orthofix
- For suppliers providing electrical components, Orthofix encourages implementation of a statistical electrical test program leveraging JEDEC standard JESD50B.01.
- Suppliers that manufacture, process, assemble, or otherwise handle electronic parts, assemblies, and equipment susceptible to damage by electrostatic discharge shall maintain an ESD control program (based on applicable standards including ANSI/ESD S 20.20 or IEC 61340-5-1).
- Strategic suppliers are expected to invest in the technologies and capabilities that will allow Orthofix to direct more spending toward those strategic suppliers.
- Development of new products or processes will require qualification. On a case by case basis, Orthofix will partner with Supplier on planning and execution of Operational Qualification (OQ) and First Production Lot Qualification (PQ). Based on the results of the qualification adjustments to the process may be required.
- To determine biocompatibility hazards, Supplier to map the manufacturing process and determine all materials used (including contact materials) in the manufacturing of Orthofix devices.

Measurements

Orthofix uses a variety of tools and metrics to set expectations and to evaluate suppliers' abilities to meet them:

- Supply and Quality Agreement – this sets quality & business level expectations.
- Relationship – the quality of interactions, measured by supplier responsiveness, level of support, and open/effective communication.
- Delivery performance – the ability to ensure an appropriate level of production/finished goods and on-time completion of services.
- Capacity/flexibility/lead time – the ability to quickly respond to changes in demand.
- Supplier Controls – a supplier management program articulating expectations consistent with those expressed in this Supplier Manual.
- Business Continuity – clear disaster recovery plans addressing potential natural and man-made business interruptions.

Value

In a focused effort to reduce health care costs, Orthofix is actively striving to deliver products that provide increasing value to patients and physicians. Orthofix expects Suppliers to:

- Competitively price new materials/services.
- Minimize development costs and support ongoing cost reduction initiatives.
- Demonstrate willingness to invest in cost reduction initiatives which enable Orthofix to realize its goals. Price reductions can be proactively achieved through lean initiatives, process/yield improvements or technology development.

Business Continuity

Orthofix expects our Suppliers to complete a formal business Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While contingency plans cannot be expected to cover all potential scenarios, we expect our Suppliers to maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

Orthofix expects its Suppliers to have a comprehensive crisis management approach to deal with potential disruptions. The approach is expected to include a plan of action, communication plans, escalation procedures, and roles and responsibilities. This plan is expected to address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for equipment, material, supplied components and labor, etc.

Service Suppliers

Expectations of production-related service suppliers (i.e. calibration, analytical/inspection labs, translation, sterilization, media, etc.) are focused on the Supplier's ability to effectively follow and perform test protocols, maintain compliance to test standards and compliance/certification to ISO 17025, while meeting responsiveness expectations and reporting requirements. In some cases, results and data provided by service suppliers are used to support a regulatory submission or product release. Orthofix considers adherence to standards and record-keeping to be critical elements in every Supplier's quality system.

Logistics and transportation service providers are expected to demonstrate value, performance (on-time and undamaged delivery) and compliance with all applicable transport and security regulations: TSA, DOT, IATA, etc. Transportation suppliers are also expected to partner with Orthofix in mitigating fuel price fluctuations and mitigating risk of damage/loss to shipments.

Non-production services suppliers (i.e. consulting, facilities, management, etc.) are expected to perform to their applicable Statements of Work, complete all deliverables on time and provide the highest quality service at competitive pricing.

Supplier as Manufacturer on Record (MOR)

In addition to expectations articulated elsewhere in this manual, suppliers designated as Manufacturer on Record have responsibilities for the following when applicable:

- Design Control Process – initiation (Design History File/Device Master Record), verification/validation activities and maintenance.
- Product literature and labeling – labeling requirements and Instructions For Use (IFU).
- Product approval – clinical requirements and regulatory submissions/approvals/maintenance.
- Post-market – external event reporting, complaint handling and device tracking.
- Specific responsibilities and requirements are defined in applicable agreements depending upon the nature of the supplier relationship.

Supplier Agreements

Orthofix generally has supply contracts, quality agreements, and/or purchase order terms and conditions with its Suppliers. These documents include the Supplier's agreement to comply with all laws applicable to the supply of services or materials to Orthofix.

It is the intention of Orthofix to establish written Supply Agreements with key Suppliers. The goal of these agreements is to establish terms and conditions for both Orthofix and the Supplier that will build and grow the businesses together. Orthofix purchase orders also contain key terms regarding the relationship.

Supply Agreements contain the terms and conditions by which Orthofix and Suppliers agree to conduct business, addressing:

- Payment terms
- Pricing and annual cost reductions
- Shipping and delivery terms
- Lead times
- Purchase order change and revision terms
- Length of agreement
- Supply assurance agreement
- Penalties for nonconformance
- Supplier change request expectations and IP ownership

Planning and Selection of Suppliers

Before committing to supply any product or service to Orthofix, there will be a contract review with the Supplier over the Orthofix requirements related to the product. This is essential to ensure that the product or service requirements are defined, order requirements are understood, and the supplier has the ability to meet the defined requirements per the acceptance of the Orthofix Purchase Order.

The level of evaluation within the selection process is based upon the potential risk of the sourcing decision, as determined by a number of factors, including but not limited to supplier history and the requirements of the particular material, component, assembly, service or finished medical device to be purchased. Strategic suppliers will be considered first for new business. When a strategic supplier cannot meet Orthofix's Quality, Technology, Service and Value expectations, then other suppliers with a proven track record of meeting these expectations will be considered.

When selecting a Supplier, Orthofix will evaluate existing and new Suppliers. The key areas evaluated are:

- Quality – capability to repeatedly produce product which meets or exceeds the technical and quality requirements of Orthofix.
- Technology – technical capability and commitment to advancing process technologies in support of Orthofix's strategic direction.
- Service – capability to meet Orthofix's production, delivery and service requirements with a demonstrated high level of support and responsiveness.
- Value – competitive pricing, year over year cost reduction capabilities and active participation in inventory management initiatives.
- Corporate Responsibility – commitment to responsible business practices.

On-site assessment may be performed in accordance with ISO-13485 or FDA QSR 210/211/820.

Quality Requirements

Supplier Expectations

- After production equivalency/process validation has been established, all changes related to Orthofix products as defined in the Device Master Record (DMR), including subcomponents, materials, and processes used on these products, must be submitted to Orthofix via Supplier Change Request (SCR) for approval prior to implementation.
- Any deviation to already manufactured product is identified, a Supplier Deviation Request (SDR) will be requested prior to shipping the lot/product.
- Any rework determined on product rejected by Orthofix will be requested by completing Orthofix rework form before executing the rework.
- Supplier is expected to meet or exceed 95% score in terms of First Pass Yield (FPY) and On-Time Delivery. A lower score may trigger corrective actions and additional on-site assessments.

Direct Part Marking and Labelling

Finished devices:

Supplier should have unique identifier to meet FDA and EUMDR requirements. Orthofix drawings/specification and agreements may have additional details around marking and labelling. Labelling requirements typically apply to implants.

Non-finished devices:

Requirements for marking and labelling will be specified in the drawing/specification or in agreements.

Measurement System Analysis (MSA)

Suppliers will develop or obtain gauges, standards and instrumentation to control their processes and to determine product conformance to specifications. Variable gauges and measurements are preferred. The Supplier will perform MSA for all new/modified gauges, measurement and test equipment. Orthofix may request the Supplier to participate in a correlation study to compare supplier measurement results against results obtained by Orthofix. A reference that can be used for MSA studies is the Automotive Industry Action group (AIAG) MSA Requirements document. Web information can be found going to www.aiag.org. As a guideline, gauge R&R with an error of >30% needs improvement unless agreed to by Orthofix.

Corrective and Preventative Action (CAPA)

Supplier will establish and maintain procedures for implementing a CAPA system in substantial compliance with ISO standards. CAPA system should address containment actions, investigation of the root cause, identification of actions needed to correct and prevent the problem from recurrence and Verification of effectiveness.

Records

All records of the quality system and manufacturing records will be maintained at the manufacturer or at other locations that are reasonably accessible to the responsible Orthofix members. These records, including any not stored at the inspection location, will be made accessible to responsible members when requested. The records will be legible and will be stored so as to prevent loss and minimize deterioration. Records stored in automated data processing systems will be backed up.

All records will be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 15 years from the date of manufacture.

Acceptance activities

The Supplier should establish procedures for acceptance activities. These procedures should include inspections, tests and verification activities for incoming material acceptance, in-process acceptance and release of finished product. These procedures should reflect the control plan and Orthofix specifications / requirements.

Procurement and Delivery

Procurement

All purchases of products and services require an Orthofix Purchase Order. To ensure Supplier has the latest revision of Orthofix documents, any drawings or specifications related to part numbers on the purchase order will be supplied with the Purchase Order.

Purchase Order confirmations are expected in writing within forty-eight (48) hours of the receipt of purchase order. The content and terms of the Purchase Order are considered accepted if a written acknowledgement is not received within ten (10) days of receipt.

When invoices are required, a valid invoice referencing the Orthofix number initiates the payment process. ACH is Orthofix's preferred method of payment. Materials and labor should be itemized on the invoice to ensure proper tax calculations.

Delivery

Supplier shall include the following with each shipment of product:

a. Packing list showing:
- Orthofix part number
- Orthofix purchase order number and line
- Revision of product
- Quantity shipped
- Lot number / serial number

b. Certificate of Conformance (C of C)
c. Certificate of Analysis (C of A) if applicable
d. Rework documentation (when applicable)
e. Written authorization of deviations (when applicable)

Supplier shall ship complete unless authorized by Orthofix. Shipping carrier and service level will be specified by Orthofix. Shipments are required to arrive at the shipping destination point specified on the Purchase Order within the allowed delivery window. Early delivery of parts are considered acceptable and no allowance over the promise date is considered acceptable. Orthofix will not pay for priority shipping due to a Supplier's delivery issues. Supplier is responsible to ensure product is delivered on or before the PO due date.

Hazardous Material:

Suppliers must follow all relevant local, state, and federal health, safety and environmental regulations and endure all proper markings are on containers and the appropriate paperwork is supplied. Copies of relevant Material Safety Data Sheets (MSDS) must be included with all shipments per OSHA regulations. Orthofix reserves the right to refuse any delivery that does not conform to these delivery requirements.

Preservation of Product (Packaging)

Packaging method and materials utilized by Supplier to transport product to Orthofix shall be appropriate to prevent damage to goods being transported. The Supplier is responsible for any damage during shipment caused by improper packaging.