

ORTHOFIX INTERNATIONAL N V

FORM SD (Specialized Disclosure Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM SD

Specialized Disclosure Report



Orthofix International N.V.

(Exact name of Registrant as specified in its charter)

Curaçao
(State or other jurisdiction of incorporation)

0-19961
(Commission File Number)

98-1340767
(IRS Employer Identification No.)

7 Abraham de Veerstraat
Curaçao
(Address of principal executive offices)

Not Applicable
(Zip Code)

Kimberley Elting
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(214) 937-2000

(Name, address and telephone number of agent for service)

Check the appropriate box below to indicate the rule pursuant to which this form is being filed, and provide the period to which the information in this form applies:

Rule 13p-1 under the Securities Act (17 CFR 240.13p-1) for the reporting period from January 1, 2016 to December 31, 2016

Section 1 – Conflict Minerals Disclosure

Item 1.01 Conflict Minerals Disclosure and Report

This Form SD of Orthofix International N.V. (the “Company”) is filed pursuant to Rule 13p-1 promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2016 to December 31, 2016.

A copy of the Company’s Conflict Minerals Report is provided as Exhibit 1.01 to this Form SD, and is publically available under the “Investors” heading of the Company’s website, www.orthofix.com.

Item 1.02 Exhibit

A copy of the Company’s 2016 Conflict Minerals Report is filed as Exhibit 1.01 attached to this Form SD.

Section 2 – Exhibits

Item 2.01 Exhibits

The following exhibit is filed as part of this report.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
1.01	Conflict Minerals Report of Orthofix International N.V.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.
Orthofix International N.V.
(Registrant)

By: /s/ Kimberley Elting
Kimberley Elting
Chief Legal Officer

Date: May 24, 2017

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
1.01	Conflict Minerals Report of Orthofix International N.V.

Orthofix International N.V.
Conflict Minerals Report
For the Reporting Period from January 1, 2016 to December 31, 2016

This Conflict Minerals Report (“Report”) of Orthofix International N.V. (“Orthofix” also referred to as “we,” “us,” or “our”) has been prepared for the reporting period from January 1, 2016 to December 31, 2016 (the “Reporting Period”), pursuant to Rule 13p-1 (the “Rule”) promulgated under the Securities Exchange Act of 1934, as amended and is being filed on Form SD. The Rule was adopted by the Securities and Exchange Commission (“SEC”) to implement reporting and disclosure requirements applicable to companies that manufacture or contract to manufacture products containing certain conflict minerals as defined under the Rule.

Conflict minerals under the Rule are defined as cassiterite, columbite-tantalite, wolframite and gold, including their derivatives, which are limited to tin, tantalum and tungsten (“Conflict Minerals” or “3TG”). The SEC reporting and disclosure requirements apply to all registrants regardless of geographic origin and whether or not they fund armed conflict. As described below, Orthofix manufactures, or contracts to manufacture, products for which 3TG are necessary to the functionality or production of those products.

The Rule states that if a company knows that any of the necessary 3TG in its supply chain originated in covered countries and are not from recycled or scrap sources, or if it has reason to believe that its necessary 3TG may have originated from the covered countries and has reason to believe that they are not from recycled or scrap sources, then the company must exercise due diligence on the 3TG minerals source and chain of custody. For the purposes of this report, covered countries, as defined in the Rule include the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia and Angola.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (“the Exchange Act”), and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,” “potential,” or “continue” or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, or the risk factors described in Part I, Item 1A under the heading Risk Factors in our Form 10-K for the year ended December 31, 2016, to reflect new information, the occurrence of future events or circumstances or otherwise.

Company Overview and Product Descriptions

We are a diversified, global medical device company focused on improving patients’ lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, we have four strategic business units (“SBU’s”): BioStim, Biologics, Extremity Fixation and Spine Fixation. Our products are widely distributed via sales representative and distributors. In addition, we are collaborating on research and development activities with leading clinical organizations such as Brown University, Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children, and the Musculoskeletal Transplant Foundation.

We identified the following SBU’s that sell products that could contain 3TG materials:

- BioStim manufactures, distributes and provides support services of market leading bone growth stimulation devices that enhance bone fusion.
 - Extremity Fixation offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine and specializes in the design, development and marketing of orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures.
 - Spine Fixation specializes in the design, development and marketing of a broad portfolio of implant products used in surgical procedures of the spine.
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Supply Chain

We rely on suppliers for various components and parts that could contain 3TG utilized in manufacturing our products. As a company in the medical device industry we do not make purchases of raw ore or unrefined 3TG, nor do we make purchases directly from the covered countries. As such, our position in the supply chain is several steps downstream from mines and smelters. Therefore, we must rely on our direct suppliers to provide information on the origin of the 3TG contained in the components and parts supplied to us – including sources of 3TG that are supplied to them from their suppliers. Further, many of our suppliers are not SEC registrants and therefore are not subject to the reporting requirements of the Rule. The quality of response and response rate from our suppliers relating to origin of custody of the necessary conflict minerals in our products has improved during the Reporting Period. Due to complexity of our products and our position within the respective supply chains of our suppliers, however, we believe additional time is needed for certain suppliers to verify the origin of the 3TG in our products. We intend to continue our due diligence efforts regarding the source and custody of the necessary conflict minerals in our products.

Reasonable Country of Origin Inquiry

We conducted a reasonable country of origin inquiry (“RCOI”) of certain suppliers to determine whether 3TG contained in our products originated from the covered countries. In determining which suppliers to survey to determine the source and chain of custody of 3TG in our products, our supply chain, engineering and operation personnel use product control data to identify parts, materials and components that we reasonably expect may contain 3TG minerals. We send a cover letter to suppliers identified as possibly providing materials containing 3TG that explains our obligations under the Rule and the Conflict-Free Sourcing Initiative’s (“CFSI”) Conflict Minerals Reporting Template (the “CMRT”), which asks them for certain information. We review and analyze the information received for completeness and consistency. Where appropriate, we ask suppliers for any clarification in determining the country of origin of 3TG being supplied. Further, we have eliminated certain suppliers from our approved vendor list for failure to show reasonable effort or improvement in their reporting data.

On the basis of the responses to our RCOI, we have reason to believe that some 3TG necessary to the functionality or production of our products may have originated from the covered countries. Accordingly, we conducted further due diligence on the source and chain of custody of the 3TG contained in products provided by our suppliers.

Due Diligence and Framework Process

Our due diligence program is designed to conform, in all material respects, with the *Organization for Economic Cooperation and Development’s Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High Risk Areas*. Our due diligence included the following five steps:

1. **Establish Strong Company Management Systems:** We have created a project team to oversee the supply chain due diligence process, which includes members from our purchasing, manufacturing and finance departments (the “3TG Project Team”). The 3TG Project Team is overseen by a senior executive of Orthofix. We maintain documents related to compliance with the Rule in an electronic database. Further, we have a company hotline that provides employees, suppliers and third parties with a mechanism to report violations of our internal policies and procedures.
 2. **Identify and Assess Risk in the Supply Chain:** We distribute the CMRT to suppliers in our supply chain to gather information on the 3TG in our manufactured products. We review each supplier response to the CMRT to assess the adequacy of the responses. Suppliers who fail to respond to our requests receive follow-up communications requesting the information. In the event supplier responses indicate that 3TG contained in the products supplied us originated from the covered countries, they are reported to the 3TG Project Team.
 3. **Design and Implement a Strategy to Respond to Identified Risks:** We have a risk management plan to address concerns that a supplier may be providing products containing 3TG sourced from the covered countries. If a supplier indicates that its products may contain 3TG sourced from the covered countries, we report the response to the 3TG Project Team which will determine appropriate follow-up actions to mitigate risks. There have been no known instances of high risk issues in the supply chain that require follow-up actions.
 4. **Carry Out Independent Third-Party Audit of Supply Chain Due Diligence at Identified Points in the Supply Chain:** We do not conduct audits of smelters or refiners and, instead, rely on the Conflict-Free Smelter Initiative’s Conflict-Free Smelter Program to perform third-party audits of smelters and refiners.
 5. **Report on Supply Chain Due Diligence:** This Conflict Minerals Report will be filed with the SEC and is publicly available under the “Investors” heading of our website, www.orthofix.com.
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Due Diligence Results

In our Conflict Minerals Report for the year ended December 31, 2015, we identified and requested completed CMRTs from the suppliers identified as providers of materials that may include 3TG to Orthofix. As part of our due diligence procedures in 2016, our 3TG Project Team further analyzed our approved vendor list with increased scrutiny and again requested completed CMRTs from these suppliers for the Reporting Period. We must rely on responses from our identified suppliers to provide us with information about the source of 3TG contained in the components supplied to us. Our direct suppliers are similarly reliant upon information provided by their suppliers.

We received responses from the majority of our suppliers indicating they did not knowingly source 3TG from the covered countries. One supplier responded that certain of its products contained materials sourced from the covered countries, but that the smelters sourcing these materials were found to be CFSI compliant as part of their due diligence procedures. The remaining suppliers either were still in the process of performing due diligence of their own supply chains or did not respond to repeated requests for information on the source of 3TG in the materials provided to us. For suppliers still in the process of performing and implementing due diligence procedures for their own suppliers, they are expected to develop, implement and document plans to remedy any potential instances of non-compliance in a timely manner. If the non-compliance cannot be resolved, we will consider terminating our relationship with the supplier.

Some suppliers responded that they were currently unable to identify the smelters and refiners used to process 3TG or the country of origin of the 3TG in their supply chain. Other suppliers provided information on all of their smelters and refiners and country of origin of 3TG for all products they supply, which does not provide us with the necessary information to match the smelter or refiner or country of origin to the specific products supplied to Orthofix, despite repeated attempts to obtain such information. Accordingly, for this Reporting Period, we do not know all the facilities used to process 3TG or the country of origin of all the 3TG used to produce our manufactured products.

Future Risk Mitigation Efforts

We intend to continue to improve our due diligence measures during the next reporting period. The steps we may pursue include, but are not limited to, the following:

- continue our due diligence efforts with direct suppliers to determine the facilities used to process the necessary 3TG and the country of origin of such 3TG;
- proactively analyze whether any 3TG materials will be present in future products that we develop, or to the extent possible, revise the materials included in existing products;
- continue to include 3TG related provisions in new or amended supplier agreements;
- further engage with suppliers to increase supplier response rates to conflict mineral related inquiries; and
- refine our strategy to respond to supply chain risks.