# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM SD

**Specialized Disclosure Report** 

# CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida (State or other jurisdiction of incorporation) 1-13165 (Commission File Number) 59-2417093 (IRS Employer Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144 (Address of principal executive office) (zip code)

Jean F. Holloway Senior Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer

(770) 419-3355

(Name and telephone number, including area code, of person to contact in connection with this report)

Check the appropriate box 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 Exchange Act (17 CFR 240.13p-1) for the reporting period from January 1 to December 31, 2016.

#### Section 1 - Conflict Minerals Disclosure

## Item 1.01 Conflict Minerals Disclosure and Report

#### **Conflict Minerals Disclosure**

This Form SD of CryoLife, Inc. (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.

#### Company Products Covered

This Item relates to Company products (i) for which "Conflict Minerals" (i.e., gold, columbite-tantalite (coltan), cassiterite, and wolframite, including their derivatives, which are limited to tantalum, tin, and tungsten) are (or in the case of the Console, as defined below, may be) necessary to the functionality or production of that product, (ii) that were manufactured or contracted to be manufactured by the Company; and (iii) for which the manufacture was completed during calendar year 2016. These products, which are referred to in this Item collectively as the "Covered Products," are the following:

# • CardioGenesis Fiber-optic Handpieces (SoloGrip® III, PEARL 5.0) ("Handpieces")

The SoloGrip III is a minimally invasive transmyocardial revascularization fiber-optic handpiece that contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber-optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle. The SoloGrip III has an easy to install connector that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation. The SoloGrip III handpiece received FDA approval in 1999 and received a CE Mark in 1997. The minimally invasive Port Enabled Angina Relief with Laser ("PEARL") 5.0 handpiece is compatible for use with Intuitive Surgical's da Vinci Surgical System. The PEARL 5.0 handpiece received FDA approval in 2007 and received a CE Mark in 2005. The "marker bands" and "pigtail assemblies" that are components of both of these Handpieces contain tantalum.

## • SolarGen 2100 Holmium: YAG Laser Console ("Console")

The Console is a Class III PMA cardiovascular therapeutic device that uses the solid state technology of the Holmium:YAG laser system to provide a stable and reliable energy platform that is designed to deliver precise energy output for the desired tissue effect. The Console is compatible with the Handpieces and implements an advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 115V power capability. The Console was approved by the FDA in 2004 and received a CE Mark in 2005. The Console is manufactured by the Company's supplier according to Company-provided specifications and contains over 800 components purchased from over 200 of the supplier's upstream suppliers. Some of those components may contain Conflict Minerals, but, as set forth in further detail below, the Company has been unable to conclusively determine whether that is the case.

# • HeRO® Graft

The HeRO Graft (Hemodialysis Reliable Outflow) is the only fully subcutaneous arterio-venous access solution clinically proven to maintain long-term access for hemodialysis patients with **central venous stenosis**. HeRO Graft is classified by the FDA as a graft, but it differs from a conventional arterio-venous graft because it has no venous anastomosis. It consists of two primary components: (i) a **proprietary ePTFE** (polytetrafluoroethylele) arterial graft component and (ii) a **proprietary venous outflow component**. A titanium connector attaches the arterial graft component to the venous outflow component. The **venous outflow component** consists of radiopaque silicone with braided nitinol reinforcement (for kink and crush resistance) and a radiopaque marker band at the distal tip. The HeRO Graft's marker band contains tantalum.

# The Company's Reasonable Country of Origin Inquiry

The Company conducted a good-faith reasonable country-of-origin inquiry ("RCOI") with respect to the Conflict Minerals contained in the Handpieces and HeRO Graft. This inquiry was reasonably designed to determine whether any of the Conflict Minerals originated in the "Covered Countries" (i.e., the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia, and Angola), and whether any of the Conflict Minerals were from recycled or scrap sources.

With respect to each of the Handpieces' and HeRO Graft's components that contain Conflict Minerals (marker bands and pigtail assemblies), the Company identified its suppliers of such components and contacted them to obtain information and documentation regarding their upstream supply chain for such components. The Company's suppliers certified, to the Company's reasonable satisfaction, that the Conflict Minerals in the Handpieces and HeRO Graft did not originate in the Covered Countries. Accordingly, the Company did not perform further due diligence or analysis with respect to the Conflict Minerals

contained in the Handpieces and HeRO Graft. A description of our RCOI and the determination reached with respect to the Handpieces and HeRO Graft are publicly available on our Company Internet website at http://phx.corporate-ir.net/phoenix.zhtml?c=80253&p=irol-confilctminerals.

# **Conflict Minerals Report**

Due to the large number of suppliers upstream of the Console supplier, as well as the relatively small percentage of the supplier's business that the Company's business represents, the Company was unable to obtain sufficient information regarding the Console's components and the supplier's upstream supply chain with respect to those components. As a result, the Company was unable to determine whether the Console contains Conflict Minerals and if so, whether they originated from Covered Countries or were from recycled or scrap sources. Accordingly, with respect to the Console, the Company undertook the due diligence process described in the Conflict Minerals Report, which is provided as Exhibit 1.01 to this Form SD and which is publicly available on the Company's Internet website at http://phx.corporate-ir.net/phoenix.zhtml?c=80253&p=irol-confilctminerals.

## Item 1.01 Exhibit

As specified in Section 2, Item 2.01 of this Form SD, the Company is hereby filing its Conflict Minerals Report as Exhibit 1.01 to this Form SD.

#### Section 2 - Exhibits

## Item 2.01 Exhibits

Exhibit No.	<u>Description</u>
1.01	Conflict Minerals Report as required by Item 1.01 and 1.02 of this Form

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, CryoLife, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRYOLIFE, INC.

By: /s/ D. Ashley Lee
Name: D. Ashley Lee Date: May 26, 2017

Executive Vice President, Chief Title:

Operating Officer and Chief

Financial Officer

# EXHIBIT INDEX

Exhibit No. Description

1.01 Conflict Minerals Report as required by Item 1.01 and 1.02 of this Form

# CryoLife, Inc. Conflict Minerals Report For the reporting period January 1, 2016 to December 31, 2016

This Conflict Minerals Report (the "Report") of CryoLife, Inc. (the "Company") has been prepared pursuant to Rule 13p-1 and Form SD (the "Rule") promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2016 to December 31, 2016.

The Rule requires disclosure of certain information when a company manufactures or contracts to manufacture products, and the minerals specified in the Rule are necessary to the functionality or production of those products. The specified minerals, which we collectively refer to in this Report as the "Conflict Minerals," are gold, columbite-tantalite (coltan), cassiterite, and wolframite (including their derivatives, which are limited to tantalum, tin, and tungsten). The "Covered Countries," for purposes of the Rule and this Report, are the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia, and Angola.

# Company Products Covered by This Report

This Report relates to the Company's CardioGenesis® SolarGen 2100 Holmium Laser Console ("Console"), which was contracted to be manufactured by the Company; for which the manufacture was completed during the reporting period; but for which the Company was unable to determine that its components did not contain Conflict Minerals that originated from the Covered Countries or from recycled or scrap sources. The Console is a Class III PMA cardiovascular therapeutic device that uses the solid state technology of the Holmium: YAG laser system to provide a stable and reliable energy platform that is designed to deliver precise energy output for the desired tissue effect. The Console is compatible with the Company's SoloGrip® III, PEARL 5.0 handpieces and implements an advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 115V power capability. The Console was approved by the FDA in 2004 and received a CE Mark in 2005. The Console is manufactured by the Company's supplier according to Company-provided specifications and contains over 800 components purchased from potentially over 100 of the supplier's upstream suppliers. Some of those components could contain Conflict Minerals, but, as set forth in further detail below, the Company has been unable to conclusively determine whether any such Conflict Minerals that might be included in the Console originated in the Covered Countries.

## Reasonable Country of Origin Inquiry

Due to the large number of suppliers upstream of the Console supplier, notwithstanding the supplier's due diligence, the Company was unable to obtain complete information regarding the Console's components and the supplier's upstream supply chain with respect to those components. As a result, the Company was unable to determine that the Console's components do not contain Conflict Minerals that may have originated in the Covered Countries. Accordingly, with respect to the Console, the Company undertook the due diligence process described below.

## The Company's Due Diligence Process

## Overview

Having concluded that the Console *could* contain Conflict Minerals and that any such Conflict Minerals *might* have originated in the Covered Countries, the Company exercised reasonable due diligence with respect to the source and chain of custody of the Conflict Minerals that might be contained in the Console. The Company's due diligence measures have been designed to conform, to the extent applicable and feasible, to the framework set forth in the Organization for Economic Co-operation and Development Due Diligence Guidance for Responsible Supply Chain of Minerals from Conflict-Affected and High Risk Areas: Second Edition, including the related supplements on gold, tin, tantalum, and tungsten (the "Guidance").

The Company's supply chain with respect to the Console is complex, and the Company understands that there are many third parties in the supply chain between the ultimate manufacture of the Console by the Company's supplier and the original sources of Conflict Minerals. In this regard, the Company does not purchase Conflict Minerals directly from mines, smelters, or refiners. It must therefore rely on its suppliers and their upstream suppliers to provide information regarding the origin of any Conflict Minerals that are included in the Console, including information regarding the applicable smelters and refiners

The Company's objective in developing and following its due diligence process was to determine which, if any, components of the Console contains Conflict Minerals, the origin and chain of custody of any such Conflict Minerals, and whether such Conflict Minerals financed or benefitted armed groups in the Covered Countries.

## Company Management Systems

As part of its due diligence efforts, the Company maintains its policy relating to Conflict Minerals (the "Policy"), which incorporates the standards set forth in the Guidance. The Policy has been reviewed and approved by the Company's senior management and presented to the Audit Committee of the

Company's Board of Directors (the "Audit Committee"). In addition, the Company's Purchasing and Legal departments have been directed by management to communicate the Policy to Company employees who have responsibilities for applying, enforcing, or communicating it internally or to relevant outside parties. In summary, the Policy provides for the following:

- The Company's support for greater transparency in the Conflict Mineral supply chain;
- The Company's expectation that its suppliers will adopt policies that (i) facilitate the Company's due diligence efforts to comply with the Conflict Minerals rules and (ii) ensure that, to the extent feasible, Conflict Minerals do not directly or indirectly finance or benefit armed groups in the Covered Countries:
- The Company's expectations of suppliers with respect to their sourcing practices and Conflict Minerals; and
- The Company's intention to evaluate suppliers' compliance with the Policy and to take such actions as the Company determines necessary to ensure compliance.

The Policy is maintained on the Company's Internet website.

In addition to maintaining the Policy, the Company undertakes a number of measures as part of its Conflict Minerals due diligence process:

- Supply Agreements. The Company will issue to suppliers of materials that contain or likely may contain Conflict Minerals a form of agreement or purchase order ('the agreements") that communicates the Company's position with respect to Conflict Minerals. The form of agreement amendment or purchase order will obligate the supplier to disclose to the Company whether any of the materials it supplies to the Company contain Conflict Minerals; and if any materials do contain Conflict Minerals, to identify the steps that supplier will take to attempt to ensure that such Conflict Minerals do not directly or indirectly finance or benefit armed groups in the Covered Countries.
- Engagement with Suppliers. The Company's RAQA and Legal Department include Conflict Minerals among the topics that are to be covered by the Company in supplier relationship development and management discussions with current and prospective suppliers of materials that could contain Conflict Minerals. Potential new suppliers will be provided access to the Policy. The Company requests that existing suppliers of materials that may contain Conflict Minerals provide information regarding their sourcing of Conflict Minerals at least annually to allow the Company to evaluate the Supplier's compliance with the Company's Policy, as well as to enable the Company to satisfy its reporting/compliance obligations.
- Records Retention. The Company's records related to Conflict Minerals, including policies, supplier agreements, and supplier correspondence will be retained for a minimum of five years.
- Risk-Awareness. In order to solicit input from interested parties regarding issues associated with the Company's use of Conflict Minerals, the Policy invites employees, suppliers, and any other interested parties to contact the Company's Legal department to raise any concerns, ask questions, or request further information about the Policy or the Company's use of Conflict Minerals.

The Company's approach with suppliers has been endorsed by its senior management, which has directed the Company's Purchasing and Legal departments to implement and continue to monitor it. The Company's management reviews with the Audit Committee its approach to Conflict Minerals.

The Company has continued to engage directly with the senior management of its Console supplier on a number of occasions to determine which, if any, of the Console's components contain Conflict Minerals and to obtain information about the upstream supply of those components, the origin of any Conflict Minerals, and whether they financed or benefitted armed groups in the Covered Countries. Over the last three years, a number of conversations took place between the Company's Legal and Purchasing departments and the supplier's management. The supplier was acquired in 2014 by a public company. The Company understands that, since then, the supplier's parent company is engaged in an ongoing, detailed due diligence process with respect to the supplier's operations and products in order to obtain information about the upstream supply of components and, ultimately, the origin of any Conflict Minerals and whether they financed or benefitted armed groups in the Covered Countries. For the reporting period, however, the supplier was unable to confirm precisely which of the Console's components contain Conflict Minerals or to conclusively determine the country of origin of those minerals. Based on information received from the supplier, the Company is optimistic that the supplier will, for the 2017 reporting period, have even greater visibility to its upstream supply chain and the origin of any Conflict Minerals used in its products. The Company plans to engage in dialog with the supplier during the remainder of 2017 to understand if it is making progress in understanding and documenting its upstream supply chain and the origin of its Conflict Minerals.

# **Supply Chain Risks**

As noted above, the Company has been unable to obtain sufficient information from the Console supplier to determine the scope and magnitude of possible risks regarding Conflict Minerals in the Consoles supplied to the Company. The Company will continue to engage in dialog with the Console supplier to determine the content of the Console's components and the identity of the supplier's upstream suppliers for any components containing Conflict Minerals, in an effort to determine the ultimate source of any Conflict Minerals. The Company will also, to the extent necessary, evaluate the due diligence of any identified smelters/refiners to be comfortable that the sourcing identified is accurate.

## Response to Identified Risks

As noted above, during 2016, the Company determined that its Console may contain Conflict Minerals, and it engaged with its supplier to conduct due diligence on the origin of any such Conflict Minerals. Despite a lack of definitive information, the Company has, for the reasons noted above, continued to trade with its Console supplier and reasonably believes that the supplier will, as part of a publicly traded company, continue to assess and understand better its Conflict Minerals supply chain. The Company management has been informed of these risks and supports the decision to continue to trade with the supplier pending further engagement with the supplier. As also noted above, the Company intends to continue to engage in dialog with the Console supplier to encourage completion of its Conflict Minerals assessment.

The following paragraphs describe how the Company intends to address any risks that are ultimately identified as a result of due diligence efforts with respect to Conflict Minerals in the Console's upstream supply chain, as well as any similar risks with respect to future suppliers and/or products;

- the Company will develop a response to the identified risks, which may include continuing to trade with the supplier while risk assessment and mitigation efforts continue;
- the Company will engage with the supplier, as appropriate, throughout the risk mitigation process; and
- the Company's Purchasing and Legal functions will report the findings of their assessment of any risks on the Console's upstream supply and the proposed course of action to management for review and approval.

# **Audits of Smelter and Refiner Due Diligence**

Through its due diligence efforts, the Company will seek to confirm (through industry validation schemes, etc.) that any smelters or refiners in its supply chain have had their due diligence processes audited by independent third parties and that the results of such audits were satisfactory.

## **Annual Reporting**

The Company will continue to report on its Conflict Minerals due diligence efforts annually, as required, as part of its annual Securities and Exchange Commission filing on Form SD. The Company's reports will include information regarding its supply chain due diligence policy, the management structure responsible for its due diligence, steps taken to identify smelters and refiners in its supply chain and assess their due diligence practices, and steps to manage and mitigate risks. The Company will also publish the audit reports, if any, associated with its due diligence practices.

## **Due Diligence Conclusions and Next Steps**

After exercising the due diligence described above, the Company was unable to determine the extent to which the Console contains Conflict Minerals and whether any Conflict Minerals that might be contained in the Console originated from the Covered Countries and/or directly or indirectly financed or benefitted armed groups in the Covered Countries. As noted above, the Company expects to continue to engage with the Console supplier to obtain current, accurate, and complete information about its supply chain and any Conflict Minerals contained in the Consoles. The Company plans to take such other steps and to improve its due diligence measures to further mitigate the risk that necessary Conflict Minerals contained in the Company's products finance or benefit armed groups in the Covered Countries.

# Forward-Looking Statements

Statements made in this Report that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include those regarding plans the Company has to engage in dialogue with the Console supplier, the Company's reasonable belief that the Console supplier will continue to assess and understand better its Conflict Minerals supply chain, how the Company intends to address risks that are identified as a result of Conflict Minerals due diligence efforts and similar risks with respect to future suppliers and/or products, plans that the Company will seek to confirm that any smelters or refiners in its supply chain have had their due diligence processes audited by independent third parties and that the results of such audits were satisfactory, and steps the Company expects to take to improve its due diligence measures and further mitigate the risk that necessary Conflict Minerals contained in the Company's products finance or benefit armed groups in the Covered Countries. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include, but are not limited to, internal and external resource constraints,, the continued implementation of satisfactory traceability and other compliance measures by our direct and indirect suppliers on a timely basis or at all, whether smelters, refiners and other market participants responsibly source Conflict Minerals, and political and regulatory developments, whether in the Covered Countries, the United States or elsewhere. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2