

CRYOLIFE INC
Form SD
May 29, 2014

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

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144

(Address of principal executive office) (zip code)

Edgar Filing: CRYOLIFE INC - Form SD

Roger T. Weitkamp

Legal Counsel, Corporate & Securities

(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, 2013.

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, 2013 to December 31, 2013.

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 2013. 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, and PEARL 8.0) (“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 PEARL 8.0 handpiece has been designed for use in a minimally invasive thoroscopic procedure. The PEARL 8.0 received FDA approval in 2012 and a CE Mark in 2005. The “marker bands” and “pigtail assemblies” that are components of all 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 (polytetrafluoroethylene) 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 identified their upstream suppliers for the components, and the Company contacted those suppliers. Those upstream suppliers provided clear information and documentation confirming, 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-govHighlights>.

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 1.02 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-govHighlights>.

Item 1.02 Exhibit

As specified in Section 2, Item 2.01 of this Form SD, the Company is hereby filing its Conflict Minerals Report as Exhibit 1.02 to this Form SD.

Section 2 -- Exhibits

Item 2.01 Exhibits

Exhibit No.	Description
-------------	-------------

1.02	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.

Date: May 29, 2014 By: /s/ D.A. Lee
Name: D. Ashley Lee
Title: Executive Vice President, Chief
Operating Officer and Chief
Financial Officer

Exhibit Index

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