

**UNITED STATES DISTRICT COURT FOR
THE SOUTHERN DISTRICT OF NEW YORK**

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A.F., AN INFANT BY AND THROUGH
HER MOTHER AND NATURAL
GUARDIAN Yael FOGEL, AND Yael
FOGEL, INDIVIDUALLY

Plaintiffs

against

SORIN GROUP USA, INC., SORIN CRM
USA, INC., CARBOMEDICS, INC., SORIN
GROUP CANADA INC., JOHN DOE
MANUFACTURING COMPANIES
AND/OR CORPORATIONS 1 THROUGH
10 WHOSE NAMES ARE UNKNOWN AT
THIS TIME WHO MANUFACTURED,
DESIGNED, PRODUCED, SOLD OR
DISTRIBUTED THE MITROFLOW LXA19
AORTIC PERICARDIAL HEART VALVE,
AND ALL ITS COMPONENT PARTS USED
DURING THE AUGUST 5, 2013 SURGERY
PERFORMED ON THE INFANT
PLAINTIFF,

Case No. 1:17-cv-05903-ER

Defendants.

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STIPULATED PROTECTIVE ORDER

The Court having found that good cause exists for issuance of an appropriately tailored confidentiality order governing the pre-trial phase of this action, and the parties having stipulated to the following provisions, it is hereby ORDERED that any person subject to this Order – including without limitation the parties to this action, their attorneys, representatives, agents, experts and consultants, acting as such, all third parties providing discovery in this action, and all other interested persons with actual or constructive notice of this Order shall adhere to the following terms, upon pain of contempt:

1. This Protective Order (the “Order”) shall apply to information, documents, excerpts from documents, transcripts, testimony, and other materials produced in the above-captioned action (the “Litigation”) pursuant to the Federal Rules of Civil Procedure and the Southern District of New York Local Rules governing disclosure and discovery.

2. Information, documents, and other materials may be designated by the producing party or a third party (“the Designating Party”) in the manner permitted in this Order. The permissible designations shall be: (a) “CONFIDENTIAL”; (b) “CONFIDENTIAL – PROTECTED HEALTH INFORMATION”; or (c) “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.” Any information, documents, excerpts from documents, and other materials designated with a permissible designation shall constitute “Designated Material” under this Order.

3. “CONFIDENTIAL” information means information, documents, or things that have not been made public by the disclosing party and that the disclosing party reasonably and in good faith believes contains or comprises (a) trade secrets, (b) proprietary or confidential business information, or (c) information implicating an individual’s legitimate expectation of privacy.

4. “CONFIDENTIAL – PROTECTED HEALTH INFORMATION” means CONFIDENTIAL information that the disclosing party reasonably and in good faith believes has not been made public and includes identifiable information about patients which is subject to the protection of the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”) – that is, health information of individuals as explained in HIPAA. Due to the nature of this case, the parties expect that some of the discovery will contain HIPAA data or mention information covered by HIPAA.

5. “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” means CONFIDENTIAL information that the disclosing party reasonably and in good faith believes is so sensitive that its disclosure to a competitor could result in significant competitive or commercial damage or disadvantage to the disclosing party.

6. Designated Material shall not be used or disclosed for any purpose other than the litigation of this action and may be disclosed only as follows:

a. *Authors and Recipients:* Designated Material, whether designated “CONFIDENTIAL,” “CONFIDENTIAL – PROTECTED HEALTH INFORMATION,” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may be disclosed to a person indicated on the face of the document or accompanying cover letter, email, or other communication to the author, addressee, or an actual or intended recipient of the document, or, in the case of meeting minutes, an attendee of the meeting.

b. *Parties:* Designated Material designated “CONFIDENTIAL” or “CONFIDENTIAL – PROTECTED HEALTH INFORMATION” may be disclosed to parties to this action or directors, officers, and employees of parties to this action, or any subsidiary or affiliate thereof, who have a legitimate need to see the information in connection with their responsibilities for overseeing the litigation or assisting counsel in preparing the action for trial or settlement. Designated Material designated “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may only be disclosed to a Witness or Prospective Witness who agrees to be bound by this Order and upon the signing of a document substantially in the form of Exhibit A. *Counsel:* Designated Material, whether designated “CONFIDENTIAL,” “CONFIDENTIAL – PROTECTED HEALTH INFORMATION,” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may

be disclosed to counsel retained specifically for this action, including any paralegal, clerical or other assistant employed by such counsel and assigned specifically to work on this action

c. *Witnesses or Prospective Witnesses:* Designated Material designated “CONFIDENTIAL” or “CONFIDENTIAL – PROTECTED HEALTH INFORMATION” may be disclosed to a witness or prospective witness in this action, but only for purposes of testimony or preparation of testimony in this case, whether at trial, hearing, or deposition, but it may not be retained by the witness or prospective witness after the conclusion of the litigation in this matter. Before Designated Material is disclosed for this purpose, each such person must agree to be bound by this Order, by signing a document substantially in the form of Exhibit A. Designated Material designated “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may only be disclosed to a Witness or Prospective Witness who agrees to be bound by this Order and upon the signing of a document substantially in the form of Exhibit A. .

d. *Consulting and Outside Experts:* Designated Material, including material designated “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” may be disclosed to an outside and/or consulting expert for the purpose of obtaining the expert’s assistance in the litigation. Before Designated Material is disclosed for this purpose, the outside expert must agree to be bound by this Order, by signing a document substantially in the form of Exhibit A. Counsel for the party showing, providing, or disclosing Designated Material to an outside expert shall be responsible for obtaining such outside expert’s agreement to be bound by this Order and signatures on a document substantially in the form of Exhibit A and retaining the original, executed copy thereof. Under no circumstances shall an expert or consultant who is a competitor or an employee of a

competitor of a party, or who is providing services to any of the foregoing, be provided access to Designated Material absent written consent from the Designating Party or Court order. “Competitors” are persons or entities endeavoring to engage in the same or similar lines of business and/or, sell the same or similar products, , as well as any persons who are actually engaged in any of these activities.

e. *Other Persons:* Designated Material may be provided as necessary to copying services, translators, court reporters, and litigation support firms. The Court, persons employed by the Court, and court reporters transcribing any hearing, trial, or deposition in this Litigation or any appeal therefrom.

7. A person having custody of Designated Material shall maintain it in a manner that limits access to the Designated Material to persons permitted such access under this Order.

8. Counsel shall maintain a collection of all signed documents by which persons have agreed to be bound by this Order.

9. Documents shall be designated by stamping or otherwise marking the documents with the words “CONFIDENTIAL,” “CONFIDENTIAL – PROTECTED HEALTH INFORMATION,” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” thus clearly identifying the category of Designated Material for which protection is sought under the terms of this Order. Designated Material not reduced to documentary form shall be designated by the producing party in a reasonably equivalent way.

10. Every person to whom Designated Material is disclosed, summarized, described, characterized, or otherwise communicated or made available, in whole or in part, shall be advised that the information is being disclosed pursuant and subject to the terms of this Order and may not be disclosed or used for purposes other than those permitted hereunder. Each such person shall

maintain the Designated Material, or information derived therefrom, in a manner reasonably calculated to prevent unauthorized disclosure. Any party issuing a subpoena to a non-party shall enclose a copy of this Order and notify the non-party that the protections of this Order are available to such non-party.

11. The parties expressly understand that certain documents and information relevant to the claims and defenses in this action may contain sensitive medical information regarding or relating to individuals who have a privacy interest in such information and that disclosure thereof would be contrary to the law and public interest and that such documents and information will be appropriately designated as ‘CONFIDENTIAL – PROTECTED HEALTH INFORMATION.’ The parties also understand documents designated as “CONFIDENTIAL – PROTECTED HEALTH INFORMATION” are subject to the Standards of Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164, promulgated pursuant to HIPAA, state law, or other similar statutory or regulatory privacy protections. This Order will constitute a Qualified Protected Order under 42 C.F.R. 164.512(e)(1)(v). The fact that a document or information is not designated “CONFIDENTIAL – PROTECTED HEALTH INFORMATION” shall not relieve the receiving party from any obligations under the statutes and regulations cited above.

12. The parties will use reasonable care to avoid designating as confidential documents or information that do not need to be designated as such. During the pendency of this Litigation, any party objecting to the designation of any Designated Material may, after making a good-faith effort to resolve any such objection, move on reasonable notice for an order vacating the designation. While such an application is pending, the Designated Material in question shall be treated as confidential pursuant to this Order. The provisions of this Order are not intended to shift

any burdens of proof, including the burden of establishing that any material constitutes validly Designated Material, which burden remains on the Designating Party.

13. The protections conferred by this Order cover not only original materials constituting Designated Material, but also any information copied or extracted therefrom, as well as all copies, excerpts, or compilations thereof, plus testimony, or presentations that might reveal Designated Material.

14. A party may submit a request in writing to the party who produced Designated Material that the designation be modified or withdrawn. If the Designating Person does not agree to the re-designation within fifteen (15) business days, the objecting party may apply to the Court for relief. Upon any such application, the burden shall be on the Designating Person to show why the designation is proper. Before serving a written challenge, the objecting party must attempt in good faith to meet and confer with the Designating Person in an effort to resolve the matter.

15. To the extent that testimony is sought concerning Designated Material during any deposition or in any other pre-trial venue, any party may exclude any person from the deposition or other venue during such testimony if the Designated Material may not be disclosed to such person under the terms of this Order. Deposition transcripts or portions thereof may be designated either (a) when the testimony is recorded, or (b) by written notice to all counsel of record, given within ten (10) business days after the Designating Person's receipt of the transcript in which case all counsel receiving such notice shall be responsible for marking the copies of the designated transcript or portion thereof in their possession or control as directed by the Designating Person. Pending expiration of the ten (10) business days, the deposition transcript shall be treated as designated. When testimony is designated at a deposition, the Designating Person may exclude from the deposition all persons other than those to whom the Designated Material may be disclosed

under Paragraph 5 of this Order. Any party may mark Designated Material as a deposition exhibit, provided the deposition witness is one to whom the exhibit may be disclosed under Paragraph 6 of this Order and the exhibit and related transcript pages receive the same confidentiality designation as the original Designated Material.

16. Any Designated Material which becomes part of an official judicial proceeding or which is filed with the Court is public. Such Designated Material will be sealed by the Court only upon motion and in accordance with applicable law. This Protective Order does not provide for the automatic sealing of such Designated Material. If it becomes necessary to file Designated Material with the Court, a party must comply with Section 3 of Judge Moses's Individual Practices by moving to file the Designated Material under seal.

17. Any person who either objects to any designation of confidentiality, or who, by contrast, requests still further limits on disclosure (such as "attorneys' eyes only," reserved for extraordinary circumstances), may at any time prior to the trial of this action serve upon the designating person and all other parties a written notice stating with particularity the grounds of the objection or request. If agreement cannot be reached promptly, counsel for all affected persons shall request a joint telephone call with the Court to obtain a ruling.

18. Notwithstanding the designation of material as "Confidential" in discovery, there is no presumption that such Confidential Discovery Material will be filed with the Court under seal. The parties shall follow § 3 of Judge Moses's Individual Practices with respect to pretrial requests for filing under seal.

19. All persons are hereby placed on notice that the Court is unlikely to seal or otherwise afford confidential treatment to any Discovery Material introduced in evidence at trial,

even if such material was previously designated as Confidential or sealed during pretrial proceedings.

20. Each person who has access to Confidential Discovery Material shall take all due precautions to prevent the unauthorized or inadvertent disclosure of such material.

21. Designated Material shall be used solely for purposes of this Litigation and shall not be used for any other purpose, including, without limitation, any business or commercial purpose, or any other litigation or proceeding; provided, however, that the foregoing shall not apply to Designated Material that is or becomes part of the public record.

22. In the event additional parties join or are joined in this Litigation, they shall not have access to Designated Material until the newly joined Party by its counsel has executed and filed with the Court its agreement to be fully bound by this Order.

23. Filing pleadings or other papers disclosing or containing Designated Materials does not waive the designated status of the material. The Court will determine how Designated Material will be treated during trial and other proceedings as it deems appropriate.

24. Upon final termination of this action, all Designated Material and copies thereof shall be returned promptly (and in no event later than forty-five (45) days after entry of final judgment), to the producing party, or certified as destroyed to counsel of record for the party that produced the Designated Material. Alternatively, the receiving party shall provide to the Designating Person a certification that all such materials have been destroyed. Notwithstanding the foregoing, counsel for the parties may keep in counsel's permanent files pleadings, motions, briefs, supporting affidavits, deposition transcripts and exhibits, other court filings, exhibits to court filings, correspondence, transcripts, Court opinions, and orders that reflect or contain

Designated Material (although the restrictions imposed herein continue to apply to such retained documents).

25. Inadvertent production of confidential material prior to its designation as such in accordance with this Order shall not be deemed a waiver of a claim of confidentiality. Any such error shall be corrected within a reasonable time.

26. Nothing in this Order shall require disclosure of information protected by the attorney-client privilege or other privilege or immunity, and the inadvertent production of such information shall not operate as a waiver. If a Designating Party becomes aware that it has inadvertently produced information protected by the attorney-client privilege or other privilege or immunity, the Designating Party will promptly notify each receiving party in writing of the inadvertent production. When a party receives notice of such inadvertent production, it shall return or destroy all copies of inadvertently produced material within three (3) business days. Any notes or summaries referring or relating to any such inadvertently produced material by the opposing party and/or third parties subject to claim of privilege or immunity shall be destroyed forthwith. Nothing herein shall prevent the receiving party from challenging the propriety of the attorney-client privilege or other applicable privilege designation by submitting a challenge to the Court. The Designating Party bears the burden of establishing the privileged nature of any inadvertently produced information or material. Each receiving party shall refrain from distributing or otherwise using the inadvertently disclosed information or material for any purpose until any issue of privilege is resolved by agreement of the parties or by the Court. Notwithstanding the foregoing, a receiving party may use the inadvertently produced information or materials to respond to a motion by the Designating Party seeking return or destruction of such information or materials. If a receiving party becomes aware that it is in receipt of information or materials which it knows or

reasonably should know is privileged, counsel for the receiving party shall immediately take steps to (i) stop reading such information or materials, (ii) notify counsel for the Designating Party of such information or materials, (iii) collect all copies of such information or materials and (iv) return such information or materials to the Designating Party.

27. The foregoing is without prejudice to the right of any party to apply to the Court for any further protective order relating to Designated Material; or to object to the production of Designated Material; or to apply to the Court for an order compelling production of Designated Material; or for modification of this Order; or to seek any other relief from the Court.

28. Nothing in this Order shall constitute an admission by any party that Designated Material is actually confidential information. Furthermore, nothing contained herein shall prejudice in any way the rights of any party to introduce into evidence at trial any document, testimony, or other evidence subject to this Order, or preclude the parties or a non-party from raising any available objection, or seeking any available protection with respect to any Designated Material, including, but not limited to, the grounds of authenticity or admissibility of evidence, materiality and privilege.

29. This Protective Order shall survive the termination of the litigation. Within 30 days of the final disposition of this action, all Confidential Discovery Material and all copies thereof, shall be promptly returned to the producing person, or, upon permission of the producing person, destroyed.

30. During the pendency of this case only, this Court shall retain jurisdiction over all persons subject to this Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt thereof.

SO STIPULATED.

For Plaintiff(s):

Signed: /s/ Daniel Woodard

Name: Daniel Woodard

Date: May 14, 2021

For Defendant(s):

Signed: /s/ Katy Koski

Signed: Katy E. Koski

Date: May 14, 2021

SO ORDERED.



EDGARDO RAMOS
United States District Judge

Dated: May 17, 2021

EXHIBIT A

I, _____, have been informed by counsel that certain documents or information to be disclosed to me in connection with the matter entitled *Fogel v. Sorin Group USA, Inc. et al.*, have been designated as confidential. I have been informed that any such documents or information labeled “CONFIDENTIAL,” “CONFIDENTIAL – PROTECTED HEALTH INFORMATION,” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” are confidential by Order of the Court.

I hereby agree that I will not disclose any information contained in such documents to any other person. I further agree not to use any such information for any purpose other than this litigation.

DATED: _____

Signed in the presence of:

_____ (Attorney)