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MAR 10 2022

JOHN C. PORTO, J.S.C.

IN RE STRATTICE HERNIA MESH LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION – ATLANTIC COUNTY

MCL CASE NO: 636

MASTER DOCKET NUMBER: ATL-L-3857-21

***CASE MANAGEMENT ORDER* #6 (PLAINTIFF AND DEFENSE PROFILE FORMS)**

This Court hereby issues the following Case Management Order to govern the form, procedure, and schedule for the completion and service of Plaintiff Profile Forms ("PPF"), Defendant Profile Forms ("DPF") and other documents referenced therein.

I. Scope of this Order

This Order applies to all parties and their counsel in cases filed or transferred in this MCL. For plaintiffs, the obligation to comply with this CMO and to provide a PPF shall fall solely to individual counsel representing a plaintiff. As with all case-specific discovery, Plaintiffs' Leadership Counsel are not obligated to conduct case-specific discovery for plaintiffs by whom they have not been individually retained.

II. Plaintiff Profile Forms

A. The PPF Form and Service

1. All plaintiffs whose cases have been or in the future are filed, transferred, and/or stand pending in this MCL shall complete and serve upon Defendants via email a completed PPF, the form of which has been agreed to by the parties and approved by the Court and is attached hereto as **Exhibit A**, along with all duly executed authorizations for the release of relevant medical records.

2. For cases pending in this MCL as of the date of this Order, all such plaintiffs shall

serve a PPF and authorizations within 60 days of Defendants' answer, but if Defendants have already answered, within 60 days of the date of this Order.[1]

3. For cases filed in this MCL after the date of this Order, all such plaintiffs shall serve a PPF and authorizations within 60 days of Defendants' answer.

4. For cases transferred into this MCL after the date of this Order, all such plaintiffs shall serve a PPF and authorizations within 60 Days of Defendants' answer ***or*** within 60 days of confirmation of MCL receipt and case opening, whichever is later.

5. The completed PPF and the duly executed authorizations shall be served upon Defendants' counsel via email at: **strattice.pff@nelsonmullins.com**. A copy of the PPF shall be sent to the Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**.

B. Authorizations

As part of the PPF process, each plaintiff will serve medical authorizations to the Defendants for each of the healthcare providers identified in the PPF so that Defendants can obtain medical records. Should Defendants desire medical records from an additional healthcare provider for a particular plaintiff, Defendants shall notify that plaintiff's counsel via email and request an authorization for that provider. That plaintiff's counsel shall have seven (7) days to respond and may (1) object to the requested authorization in writing via email, or (2) provide the requested authorization to the Defendants. If a plaintiff fails to respond to the request or objects and Defendants still desire the authorization, Defendants shall then request a meet and confer which shall take place within 14 days. Following the completion of the meet and confer process and absent any agreement, Defendants may file a Motion to Compel and the plaintiff may file a

[1] If prior to this MCL a plaintiff had already responded to Interrogatories and/or Requests for Production and already provided some or all information requested in the PPF, a plaintiff may incorporate by reference such prior discovery responses where applicable in the PPF. Additionally, this Order shall not be construed to require any plaintiff to re-submit any authorizations in any case where authorizations have already been submitted.

response within the time allotted by New Jersey Rules of Court or by order of the Court.

C. Supplements and Amendments

Each plaintiff shall remain under a continuing duty to supplement the information provided in the PPF.

III. Defendant Profile Forms

A. The DPF Form and Service

1. For all cases that have been – or in the future are – filed, transferred, and/or stand pending in this MCL, Defendants shall complete and serve a Defense Profile Form ("DPF"), the form of which has been agreed to by the parties and approved by the Court and is attached hereto as **Exhibit B**, along with any and all attachments and files necessary to provide complete information requested within the DPF.

2. Defendants shall serve a DPF within 45 days of the receipt of a PPF.

3. Receipt of an allegedly deficient PPF shall not serve as a basis for failure to provide a DPF. Rather, if Defendants are in receipt of an allegedly deficient PPF, Defendants shall nonetheless complete a DPF and, if Defendants claim an inability to complete portion(s) the DPF due to an informational deficiency in a PPF, Defendants shall state that with specificity within the applicable portion(s) of the DPF.

4. The completed DPF shall be served upon each plaintiff's counsel of record along with a copy of the DPF to the Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**.

B. Supplements and Amendments

Defendants shall remain under a continuing duty to supplement the information provided in the DPF.

IV. Deficiency Dispute Resolution

1. The provisions of this Section shall apply to all plaintiffs and Defendants.

2. If any party ("Producing Party") fails to produce a PPF or DPF within the time required by this Order or serves a PPF or DPF that is deemed to be deficient by the receiving party ("Receiving Party"), the Receiving Party shall notify the Producing Party's counsel of the failure to serve a PPF or DFP or of any alleged deficiency by email. A courtesy copy of the email identifying the alleged deficiency shall be sent to Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**. In the email, the Receiving Party shall identify the case name, docket number, the 15-day deadline date, and include sufficient detail regarding the alleged deficiency(ies). Upon receipt of such written notice, the Producing Party shall then have 15 days to serve a PPF or DPF or to cure or otherwise respond to the alleged deficiency.

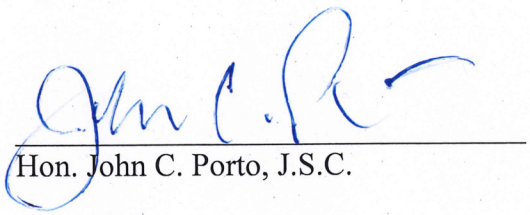
3. Before the 15 days expires, the Producing Party may request one extension of an additional 15 days to serve a complete or amended PPF or DPF, which shall not be unreasonably withheld, making the due date for such PPF and DPF 30 days after the original deficiency notice was served. Such requests must be made by the Producing Party via email to the Receiving Party's counsel of record before the expiration of the 15 day deadline, with a courtesy copy sent to the Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**.

4. With regard to deficiency disputes (which includes failure to return authorization(s)), if the Producing Party fails to respond or otherwise cure the alleged deficiency, the Receiving Party may request a meet and confer via email. A courtesy copy of the email shall be sent to the Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**. The parties' meet and confer shall be completed within 15 days of the request, absent agreement of the parties. Following the conclusion of the meet and confer period, should the Producing Party fail to

participate in the meet and confer process or otherwise cure the deficiency in a manner satisfactory to the Receiving Party, absent agreement of the parties, the Receiving Party may file a Motion to Compel the allegedly deficient discovery information in the individual case docket, with a courtesy copy sent via email to the Producing Party's counsel and to Plaintiffs' Leadership Counsel at **strattice@kbaattorneys.com**. The Producing Party may file a response within the time allotted by New Jersey Rules of Court or by order of the Court.

IT IS SO ORDERED

Dated: March 10, 2022



Hon. John C. Porto, J.S.C.

IN RE STRATTICE MESH LITIGATION	: SUPERIOR COURT OF NEW JERSEY : LAW DIVISION: ATLANTIC COUNTY : : MCL CASE NO. 636 : : MASTER DOCKET NUMBER: ATL-L-3857-21 : : :

PLAINTIFF PROFILE FORM

In completing this Plaintiff Profile Form, you must provide information that is true and correct to the best of your knowledge. The Plaintiff Profile Form shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

I. CASE INFORMATION

Caption:_____ **Docket No.:** _____

Primary Attorney Contact (name, address, phone, and email):

_____

II. PLAINTIFF INFORMATION

Name of Injured Individual_____ ☐**Male** ☐**Female**

Date of Birth:_____ **Last 4 of Social Security No.:** _____

Address:_____

Occupation: _____

Spouse Name: _____ **Loss of Consortium Claim?** ☐ **Yes** ☐ **No**

Name of Estate Representative if Individual Implanted with Strattice is Deceased: _____

**** Please submit the death certificate and letter of administration/representation if the individual implanted with Strattice is deceased.

III. STRATTICE MESH DEVICE & IMPLANT AND REVISION INFORMATION

Date Strattice Mesh Implanted: (*For each Strattice implant, submit the implant operative report and any medical evidence of product identification (product ID sticker)).*

_____

Type of Hernia (e.g., inguinal, ventral, incisional, etc.): _____

Lot and Reference Numbers: _____

_____

Implanting Surgeon: _____

Medical Facility Where Strattice Mesh Implanted & Last Known Address of Facility:

_____

Date of explant, revision, recurrent or injury surgery: (***For each removal/revision, submit the operative report, any pathology report, and any medical evidence identifying the product removed/revised.***)_____

Description of Surgery(ies): _____

_____

Name of Explanting/Revision Surgeon(s): _____

_____

Medical Facility Name & Address Where Explant, Revision, Recurrent or Injury Surgery(ies) Occurred: _____

_____

_____

_____

***Attach additional pages as needed to identify other responsive implant or removal/revision procedures.

IV. OUTCOME ATTRIBUTED TO DEVICE

A. Describe in detail the injuries, including any emotional or psychological injuries, that you claim resulted from the implantation of the Strattice mesh: _____

_____

_____

B. Please list all doctors or other healthcare providers you have seen for treatment of any of the alleged injuries listed above.

Provider Name, Address, and Specialty	Condition Treated	Approximate Dates of Treatment

***Attach additional pages as needed to describe injuries or identify other responsive health care providers.

C. Other than the Strattice product(s) that is the subject of your lawsuit, have you ever been implanted with any other hernia mesh products? ☐ **Yes** ☐ **No**

If Yes, please provide the following information:

1. Product Name(s) and Lot Numbers: _____

_____

2. Date of implantation procedure(s) and name and address of implanting doctor(s):_____

_____

**** Please submit all implant report(s) and product Identification Documentation for any implants listed in C. above.

D. Have you filed a lawsuit or asserted any claim related to any of the hernia mesh products listed in Section C? ☐ **Yes** ☐ **No** ☐ **N/A**

If Yes, identify the court, docket number, and the year the claim/lawsuit was filed:

_____

E. Have any other products listed in Sections C or D above been revised or removed?
☐ **Yes** ☐ **No**

If yes, identify when the other products were revised or removed and your understanding as to the reason for the revision or removal.

_____

_____

**** Please submit all operative report(s) and pathology records, if any, showing the removal or revision.

3. To the extent not already listed in Section B. above, please list all doctors or other healthcare providers you have seen for treatment of any of the alleged injuries subject to claims in This Court:

Provider Name, Address, and Specialty	**Condition Treated**	**Approximate Dates of Treatment**

4. Are you making a claim for lost wages, lost earning capacity, and/or lost future earnings?
☐ **Yes** ☐ **No**

If yes, describe in detail the lost wages, earning capacity, or future earnings you are claiming:

_____

_____

5. To the best of your knowledge, have you been approved to receive or are you receiving Medicare benefits due to age, disability, condition, or any other reason or basis?

   ☐ **Yes** ☐ **No** ☐ **Do Not Know**

   If yes, please specify the date on which you first became eligible: _____

   (If the answer is NO, you do not need to return the CMS (Medicare) release.)

   [Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

6. Have you been approved to receive or received workers' compensation (WC), Social Security Disability (SSI or SSD) benefits, or other state or federal disability benefits from 2008 to the present?

   ☐ **Yes** ☐ **No**

   If yes, please specify the following:

   a. Date (or year) of approval: _____

   b. Type of benefits received: (check all applicable)

   ____ Workers' Compensation ____ Social Security Disability **

   ____ Other State or Fed Disability (please identify agency from which disability benefits sought):

   d. The nature of the claim and specific injuries/disability alleged:

   _____

   f. Whether you are currently receiving any benefits as a result of the claim:

   _____

   (**If you have not applied for or received Social Security Disability benefits, you do not need to sign and return the Social Security Administration (SSA) release.)

AUTHORIZATIONS AND MEDICAL RECORDS TO BE PRODUCED

Submit ONE (1) SIGNED ORIGINAL copy of each of the records authorization forms attached as Ex. A. These authorization forms will authorize the records vendor selected by the parties to obtain those records identified in the authorizations from the providers identified within this Plaintiff Profile Form.

Submit a copy of any medical records, including those referenced herein, in your possession, custody, or control (including any medical records in your attorney's possession) related to the claims and/or alleged injuries in this case.

Signed this _____ day of _____ 2022

_____

[Plaintiff's Counsel of Record]
Firm Name
Firm Address
Firm Address 2
Phone

Email

IN RE STRATTICE MESH LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY MCL CASE NO. 636 MASTER DOCKET NO. ATL-L-3857-21 Civil Action **DEFENDANT PROFILE FORM**

DEFENDANT PROFILE FORM

For each case in which a Plaintiff Profile Form ("PPF") was served, the Defendants must complete this Defendant Profile Form ("DPF") in accordance with the schedule established by the applicable Case Management Order. In completing this Defendant Profile Form, Defendants must answer every question.

I. CASE INFORMATION

This DPF pertains to the following case:

Caption: _____

Civil Action No.: _____

Court in which action was originally filed: _____

II. CONTACTS WITH PLAINTIFF'S HEALTHCARE PROVIDERS

In each PPF served on Defendants, Plaintiff has identified each physician and/or healthcare provider ("Healthcare Providers") who implanted Defendants' hernia mesh product(s) that are subject to claims in this lawsuit and who removed/explanted and/or revised Defendants' hernia mesh product(s).

With respect to each of those Healthcare Providers, Defendants shall provide the following information:

A. If Defendants ever retained any of these Healthcare Providers as a "thought leader," "Key Opinion Leader," a member of a "speaker's bureau," a "clinical investigator," a "consultant," a "panelist," or in any other capacity, please provide the following information:

Name of Healthcare Provider Retained	**Applicable Defendant(s)**	**Date(s) Healthcare Provider was Retained**	**Payments Received by Healthcare Provider (Including expenses, honoraria, fees, travel expenses, meals, or any other payment or thing of value)**

B. To the best of your ability, identify and/or estimate the total number of calls that each sales representative made to each of Plaintiff's Healthcare Providers regarding the hernia mesh products at issue in this case and the periods of time those calls occurred. For clarification, the parties agree that you are not required to search individual sales representative custodial files in order to respond to this request.

C. Identify the name and last known address of the sales representative who was present for Plaintiff's hernia mesh implant surgery and/or sold the hernia mesh product at issue in this case and the years they called on Plaintiff's Healthcare Providers.

D. Identify whether a "Dear Doctor" or "Dear Healthcare Provider" letter was set to Plaintiff's Healthcare Provider(s) regarding the hernia mesh product at issue in this case. If yes, please identify the date of that letter and the sender.

III. COMMUNICATIONS WITH FDA

A. Identify all MedWatch and/or MAUDE Adverse Event Reports ("AER") and/or any other documents submitted by anyone to the FDA with regard to Plaintiff with respect to the injuries and claims asserted by Plaintiff in the underlying Complaint.

IV. COMMUNICATIONS WITH PLAINTIFF

A. Identify any direct contact, either written or oral, between Plaintiff and/or Plaintiff's representative and any employee and/or representative of Defendants, including, but not limited to pre-operative inquiries, and post-operative complaints. This request specifically includes, but is not limited to, calls to any Defendant hotline or Assurance Department.

B. As to the implant procedure(s), where Defendants' hernia mesh product(s) were implanted in Plaintiff, state, to the extent known, whether any of Defendants' sales representatives or any other representatives were in attendance at the implantation procedure.

IV. DEVICE AND FACILITY RELATED INFORMATION

A. Identify the lot number(s), date of manufacture, and location of manufacture for all Defendants' hernia mesh device(s) implanted into Plaintiff.

B. Identify the date of shipping and sale, and the person or entity purchasing, each of Defendants' hernia mesh device(s) implanted in Plaintiff.

V. DOCUMENT REQUESTS

Defendants are requested to produce the following documents which include, but is not limited to, paper, email, electronically stored information, video, audio, spreadsheets, and/or any other communication or record responsive to this DPF.

A. A true and complete copy of all underlying documentation containing all information set forth in Sections I. through IV. above and any and all documents collected, referred to, or used in forming the responses thereto.

B. A true and complete copy of the complaint file relating to Plaintiff's claims, or, in the alternative if already produced, provide the bates number for the file.

C. A copy of the iteration of the IFU that accompanied the specific hernia mesh product(s) that was implanted into Plaintiff.

D. Identify by bates and produce any "Dear Doctor" or "Dear Healthcare Provider" letter was set to Plaintiff's Healthcare Provider(s) regarding the hernia mesh product at issue in this case.

Dated: _____

_____

Defendants' Counsel of Record
Name
Address
Address 2
Phone
Email