IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP. PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION

MDL 2387

THIS DOCUMENT RELATES TO
ALL CASES INCLUDING COLOPLAST WAVE 1 CASES

PRETRIAL ORDER # 105

(Order re: Amending PTO # 12 and Adopting Plaintiff Fact Sheets and Defendant Fact Sheets)

PTO # 12 (Plaintiff Profile Forms, Plaintiff Fact Sheet, and Defendant Fact Sheets) contains provisions related to the Plaintiff Fact Sheet ("PFS") and the Defendant Fact Sheet ("DFS"). It is **ORDERED** that PTO # 12 is amended to omit paragraphs 2.a, 3.a (first paragraph only) and 3.b. In light of the court's recent decision to enter wave orders in this MDL, those provisions referring to bellwether cases and subgroups of bellwether cases are no longer applicable. However, the remaining provisions in PTO # 12 related to Plaintiff Profile Forms, PFSs and DFSs remain in place.

The parties have agreed to and submitted for entry, a proposed PFS with Verifications and Authorizations¹ and a proposed DFS, attached as Exhibits A and B respectively. The court adopts the PFS and DFS for use in the Coloplast MDL wave and other cases, where applicable, and it is **ORDERED** as follows:

¹ The PFS, Verifications and Authorizations can be found on the court's website at <u>www.wvsd.uscourts.gov</u> under

the Coloplast MDL, Plaintiff Fact Sheet. The Authorizations are the same as those used for the Plaintiff Profile

Form.

(1) The PFSs, Verification(s) and Authorizations must be submitted to the plaintiffs' leadership and Coloplast and/or Mentor counsel (where applicable) at the following addresses electronically:

Plaintiffs - <u>rburnett@rburnettlaw.com</u> - (Riley Burnett)

<u>lcausey@salim-beasley.com</u> – (Lisa Causey-Streete)

<u>jsmostyn@mostynlaw.com</u> – (Steve Mostyn)

<u>mholbrook@holbrooklaw.com</u> – (Mark Holbrook); and crcallahan@mostynlaw.com - (Cossette Callahan)

Coloplast - <u>ColoplastMesh@fulbright.com</u> - (Lana Varney)

Mentor - <u>MentorPPFs@tuckerellis.com</u> - (Dustin Rawlin)

(2) Defendant(s) must submit a completed DFS where required to the plaintiffs electronically at:

<u>rburnett@rburnettlaw.com</u> - (Riley Burnett) <u>lcausey@salim-beasley.com</u> - (Lisa Causey-Streete) <u>jsmostyn@mostynlaw.com</u> - (Steve Mostyn) <u>mholbrook@holbrooklaw.com</u> - (Mark Holbrook); and crcallahan@mostynlaw.com - (Cossette Callahan)

and defendant(s) must serve a completed DFS in each individual case where required on the individual plaintiff's counsel in that particular case.

(3) Any party who fails to comply with the PFS and DFS obligations under this order must comply with the provisions contained in PTO # 12 at paragraphs 2.c and 3.d.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2387 and in the Coloplast Wave 1 Cases. In cases subsequently filed in this district after 2:16-cv-05443, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide

by all pretrial orders previously entered by the Court. The orders may be accessed through the CM/ECF system or the Court's website at www.wvsd.uscourts.gov.

ENTER: June 21, 2016

JOSEPH R. GOODWIN UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

 .	Name of Plaintiff	
Civil Action No.:		
THIS DOCUMENT RELATES TO		
LITIGATION		
PRODUCTS LIABILITY		
PELVIC SUPPORT SYSTEMS		
IN RE: COLOPLAST CORP.	MDL No. 2387	

PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of a pelvic mesh product manufactured or sold by Coloplast Corp. must complete this Plaintiff Fact Sheet. In completing this Fact Sheet, you are under oath and must answer every question and provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can and then state that your answer is incomplete and explain why as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact sheet herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Defendants from seeking additional documents and information on a reasonable, case-by-case basis pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, please use the following definition: "healthcare provider" means any doctor, physician, surgeon, pharmacist, hospital, clinic, center, physician's office, infirmary, medical or diagnostic laboratory, or other facility that provides medical care or advice, and any pharmacy, x-ray department, radiology department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in the diagnosis, care and/or treatment of you.

In filling out this form, the terms "You" or "Your" refer to the person who received pelvic mesh product(s) manufactured or sold by Coloplast Corp. and who is identified in Question I.1 (a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary.

I. BACKGROUND INFORMATION

		Prior Address	Dates You Lived At This Address
	•	resses from 2000 to the present:	n 10 years, provide each of your prior residence
4)			10
3)	You	r date of birth:	
2)	You	r Social Security Number:	
	c.	The name and address of your prim	ary attorney:
	b.	1 (a) above, and the relationship of	this form, if different from the person listed in the person completing this form to the person
	a.	name:	ed the pelvic mesh product(s), including maiden
1)	Plea	se state:	

5)	Have you ever b	een m	arried? Yes N	lo		
	If yes, provide marriage to each		mes and addresses on.	of each spouse an	d the inclusiv	re dates of your
6)	Do you have chi	ldren?	Yes No			
	If Yes, please pr	ovide	the following infor	mation with respec	ct to each child	1:
Full	Name of Child]	Date of Birth	Home Address (different from yours)	`	Vhether ical/Adopted
7)	Identify the narrelationship to y		d age of any per	son who currently	resides with	you and their
8)		-	and post-secondary following informa		_	vith high school
	Name of School		Address	Dates of Attendance	Degree Awarded	Major or Primary Field

Employer Name	Addresses	Job Title/ Description of Duties	Dates of Employment	Salary/Ra of Pay
If Yes, please	er served in any branch of e provide the following in and dates of service, ran	nformation: nk upon discharge and	d the type of dis	charge you
_	ı discharged from the m physical, or psychiatric c	•	•	ing to your

II. CLAIM INFORMATION

1) Please complete the following chart for each implanted Coloplast Corp. pelvic mesh product. Insert additional lines as necessary.

Pelvic Mesh Product and lot number (if sticker	Date of Implant and Name and Location	Reason for Implant	Implanting Doctor and Address
affixed, so indicate)	of Implanting Facility		
Product No. 1:			
Product No. 2:			
Product No. 3:			

col	r each pelvic mesh product identified above, describe your understanding of the medical ndition for which you received the pelvic mesh product(s), including a detailed scription of the symptoms, if any, for which the device was intended to treat:
im an	r each Coloplast Corp. pelvic mesh product identified above, indicate if, prior to plantation, you received any written and/or verbal information or instructions, including risks or complications that might be associated with the use of the product(s)? Yes Don't Know
If '	Yes:
a.	Provide the date you received the written and/or verbal information or instructions:
b.	Identify by name and address the person(s) who provided the information or instructions:
c.	What information or instructions did you receive?

		f you have copies of the written information or instructions you received, please attach
	C	opies to your response.
4)	For e	each Coloplast Corp. pelvic mesh product(s) that remains implanted in you:
		Has any doctor recommended removal of the pelvic mesh product(s)? Yes No
		f Yes, Identify by name and address the doctor who recommended removal and state our understanding of why the doctor recommended removal:
5)	part?	e any of the Coloplast Corp., pelvic mesh product(s) been removed, in whole or in No Don't Know
	If Yo	es, for each pelvic mesh product removed provide:
	a.	On what date, where and by whom (doctor) was the pelvic mesh product(s), or any portion of it, removed?
	b.	Explain why you consented to have the pelvic mesh product(s), or any portion of it, removed?
	c.	Does any medical treater, physician or anybody else on your behalf have possession of any portion of the pelvic mesh product® that was previously implanted in you and removed? Yes No Don't Know
	I	f Yes, please state name and address of the person or entity having possession of same.
6)	-	you claim that you suffered bodily injuries as a result of the implantation of any plast Corp., pelvic mesh product(s)? Yes No
	If Yo	es:
	a.	Describe the bodily injuries, including any emotional of psychological injuries, that you claim resulted from the implantation of the pelvic mesh product(s).

claim in your la	wsuit to have resulted from the p	pelvic mesh product(s)?
When did you f	irst attribute these bodily injurie	s to the pelvic mesh product(s)?
you first saw a		a, please state approximately when those bodily injuries you claim to oduct(s):
Yes No		ed to your claimed bodily injuries?
Are you current		a doctor or healthcare provider for
	list all doctors you have seen f	For treatment of any of the bodily
Name and	Condition Treated	Annrovimate Dates of

Provider Name and	Condition Treated	Approximate Dates of
Address		Treatment

	Yes No _	•	odily injuries you listed above?
	If Yes, please p	provide the following:	
_	Name and	Condition Treated	Approximate Dates of Treatment
have y Yes _	ou been implant No	ed with any other pelvic mes	(s) that are the subject of your had products?
have y Yes If Yes	you been implant No s, please provide	the following information:	h products?
have y Yes If Yes	you been implant No s, please provide	ed with any other pelvic mes	h products?
have y Yes _ If Yes a.	vou been implant No s, please provide Product Name(the following information: s):	h products?
have y Yes _ If Yes a. b.	vou been implant No s, please provide Product Name(Date of implan	the following information: s):	and address of implanting doc
have y Yes _ If Yes a. b.	vou been implant No s, please provide Product Name(Date of implan	the following information: (s): tation procedure(s) and name	and address of implanting doc

Are y	ou making a claim for lost out-of-pocket expenses?
Yes _	No
If Yes	s, please identify and itemize all out-of-pocket expenses you have incurred:
	nyone filed a loss of consortium claim in connection with your lawsuit regarding mesh product(s)?
Yes _	No
	s, identify by name and address the person who filed the loss of consortium clared the relationship of that person to you, and state the nature of the claim:

Please indicate whether the consortium plaintiff is alleging any of the claimed damages set forth below and itemize the alleged damages/expenses:

Claims	Yes/	Itemized Damages/Expenses
	No	
Loss of services of spouse		Not applicable
Impaired sexual relations		Not applicable
Lost wages/ lost earning		
capacity		
Lost out-of-pocket expenses		
Physical injuries		Not applicable
Psychological Injuries/		Not applicable
Emotional Injuries		
Other		Not applicable

Please list the name and address of any healthcare providers the consortium plaintiff has seen for treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to the loss of consortium claim.			
Have you or anyone acting on your behalf had any communication, oral or written, with any of the defendants or their representatives, other than your attorneys?			
Yes No Don't Know			
If Yes, set forth the date of the communication, the method of communication, the name of the person with whom you communicated, and the substance of the communication between you and any defendants or their representatives:			
III. MEDICAL BACKGROUND			
Provide your current age: Height Weight			
At the time you received each pelvic mesh product(s), please state:			
Your age Your approximate weight			
State number of vaginal births you have had?			
State the number of cesarean section births you have had?			
In chronological order, list any and all pelvic and/or abdominal surgeries you had an any			

Doctor or Healthcare Provider Involved (including address)	Description of Surgery Hospitalization	Approximate. Date

In chronological order, list any and all other surgeries, procedures, or hospitalizations you had in the 10 year period **BEFORE** implantation of the pelvic mesh product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and providing the approximate date(s) for each. Insert additional rows as necessary.

Doctor or Healthcare Provider Involved (including address)	Description of Surgery Hospitalization	Approximate. Date

7) In chronological order, list any and all surgeries, procedures, or hospitalizations you had **AFTER** the implantation of the pelvic mesh product(s); identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each. Insert additional rows as necessary.

Doctor or Healthcare Provider	Description of Surgery/	Approximate
Involved (including address)	Hospitalization	Date

8) To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital, or other health care provider from which you have received medical advice and/or treatment for the past **10 years.** Insert additional rows as necessary.

Name and Specialty	Address	Approximate Dates/Years of Visits

9)	Please describe your physical activities associated with daily living, physical fitness,
	household tasks, and employment-related activities before the implantation of each pelvic
	mesh product.

10)	Please describe your physical activities associated with daily living, physical fitness,
	household tasks, and employment-related activities after the implantation of the pelvic
	mesh product(s).

11) To the best of your knowledge, have you suffered from any of the following:

Medical Condition		Sought treatment for?	Indicate whether condition occurred pre-implant, post- implant or both (explain, if necessary)
Adhesions	Yes No	Yes No	Pre Post
Bleeding or Clotting Disorders If Yes , please specify disorder:	Yes No	Yes No	Pre Post
Bowel Obstruction	Yes No	Yes No	Pre Post
Bowel Perforation	Yes No	Yes No	Pre Post
Cancer If Yes , please specify type:	Yes No	Yes No	Pre Post
Chronic Constipation	Yes No	Yes No	Pre Post
Collagen Disorder/Deficiency	Yes No	Yes No	Pre Post
Connective Tissue Disorder If Yes , please specify disorder:	Yes No	Yes No	Pre Post
Crohn's Disease, Irritable Bowel Syndrome, Ulcerative Colitis, or Chronic Diarrhea	Yes No	Yes No	Pre Post

If Yes , please specify which condition and treatment prescribed:			
Cystocele	Yes No	Yes No	Pre Post
Diabetes	Yes No	Yes No	Pre Post
Diverticulitis	Yes No	Yes No	Pre Post
Dyspareunia	Yes No	Yes No	Pre Post
Enterocele	Yes No	Yes No	Pre Post
Fistulas	Yes No	Yes No	Pre Post
Hernias	Yes No	Yes No	Pre Post
Hypertension or High Blood Pressure	Yes No	Yes No	Pre Post
Hypotension or Low Blood Pressure	Yes No	Yes No	Pre Post
Immune System Disease or Dysfunction including HIV/AIDS If Yes , please specify condition:	Yes No	Yes No	Pre Post
Malnutrition	Yes No	Yes No	Pre Post
Muscle or Muscle-Wasting Disorder If Yes , please specify disorder:	Yes No	Yes No	Pre Post
Neuromuscular Disease or Disorder	Yes No	Yes No	Pre Post

If Yes , please specify disorder:			
Obesity	Yes No	Yes No	Pre Post
Pelvic Trauma			
If Yes , please describe trauma:	Yes No	Yes No	Pre Post
Pelvic Tumors or Fibroids	Yes No	Yes No	Pre Post
Peritonitis/Sepsis	Yes No	Yes No	Pre Post
Rectocele	Yes No	Yes No	Pre Post
Recurrent or Chronic Vaginal or Bladder Infections If Yes , please specify location and nature of infections:	Yes No	Yes No	Pre Post
Recurrent Vaginal Pain If Yes , please describe the nature of pain experienced:	Yes No	Yes No	Pre Post
Urinary Incontinence	Yes No	Yes No	Pre Post
Urinary Retention	Yes No	Yes No	Pre Post
Uterine Prolapse	Yes No	Yes No	Pre Post
Vaginal Vault Prolapse	Yes No	Yes No	Pre Post
Wound Healing Problems	Yes No	Yes No	Pre Post

If Yes , please explain:			
Any other disease of the gut, intestines, or bowels	Yes No	Yes No	Pre Post
If Yes , please specify condition (s):			

* * * * * * * * * * * * * *

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

	through the present?	Yes	_ No
	If Yes, specify the disease, date of onset, medication/treatn and current status of condition:	nent, trea	ting physician
b)	Have you been diagnosed with and/or treated for any dependency for the one year prior to the implantation product(s) through the present?	n of the	
	If Yes, specify type and time period of dependency, type name of treatment provider, and current status of condition		nent received,
c)	Have you experienced, been diagnosed with or been treated conditions including depression, anxiety or other emdisorders in the 5 year period before implantation of the through the present?	otional o pelvic m	or psychiatric
	If Yes, specify condition, date of onset, medication/treatmand current status of condition:	ent, trea	ting physician

18

* * * * * * * * * * * * * *

estrogen
and the

List each prescription medication you have taken **for more than 3 months at a time, within the last 5 years prior to implant to present,** giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

Medication and Dosage	Pharmacy (Name and Address)

IV. <u>INSURANCE INFORMATION</u>

1) Provide the following information for any past or present medical insurance coverage within the last 10 years:

Insurance Company (Name and Address)	Policy Number	Name of Policy Holder/Insured (if different than you)	Approx. Dates of Coverage		

Yes	No Don't Know
	es, please state when the denial occurred, the name of the life insurance company, and ompany's reason for denial:
	ne best of your knowledge, have you been approved to receive or are you receiving
	care benefits due to age, disability, condition or any other reason or basis?
Yes	No

[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 at that time. 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.]

V. PRIOR CLAIM INFORMATION

1)		Have you filed a lawsuit or made a claim in the last 10 years, other than in the present sui relating to any bodily injury?						
	Yes	No						
	If Yo	es, please specify the following:						
	a)	Court in which suit/claim filed or made:						
	b)	Case/Claim Number:						
	c)	Nature of Claim/Injury:						
2)		Have you applied for workers' compensation (WC), Social Security disability (SSI or SSD benefits, or other state or federal disability benefits within the past 10 years?						
	Yes	No						
	If Yo	es, please specify the following:						
	a)	Date (or year) of application:						
	b)	Type of benefits sought						
	c)	Agency/Insurer from which you sought the benefits:						
	d)	The nature of the claimed injury/disability:						
	e)	Whether the claim was accepted or denied:						

VI. FACT WITNESSES

1) Please identify all persons who you believe possess information concerning your injury(ies) and current medical conditions, other than your healthcare providers, and please state their name address and his/her/their relationship to you:

Name	Address	Relationship to You	Information you Believe Person Possesses

VII. <u>IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY</u> <u>STORED INFORMATION</u>

For the period beginning three years prior to implantation of the pelvic mesh product(s) to
present, please identify all research, including on-line research, you have conducted regarding the
subjects of this litigation, including the implantation of the pelvic mesh product(s), the injurie
and/or damages you claim resulted from the implantation of the pelvic mesh product(s), or you medical or physical condition. Identify date, time, and source, including any websites visited
Research conducted to understand the legal and strategic advice of your counsel is not considered responsive to this request.
esponsive to this request.

-		
_		VIII. DOCUMENT REQUESTS
1)	RFI	EASES.
1)	NOT	TE: Please sign and attach to this Fact Sheet the authorizations for the release of rds appended hereto.
2)	poss	CUMENTS. State whether you have any of the following documents in your ession, custody, and/or control. If you do, please provide a true and correct copy of such documents with this completed Fact Sheet.
	a)	If you were appointed by a court to represent the plaintiff in this lawsuit, produce any documents demonstrating your appointment as such.
		i. Not Applicable
		ii. The documents are attached [OR] I have no documents
	b)	If you represent the estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).
		i. Not Applicable
		ii. The documents are attached [OR] I have no documents
	c)	Produce any communications (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the pelvic mesh product(s) or subject litigation, including but not limited to all letters, e-mails, blogs, Facebook posts, tweets, newsletters, etc. sent or received by you. Research conducted to understand

the legal and strategic advice of your counsel is not considered responsive to this request.

	1.	Not Applicable				
	ii.	The documents are attached [OR] I have no documents				
d)	phot refer injur evid the p	duce all documents (including journal entries, lists, memoranda, notes, diaries), ographs, video, DVDS or other media, including all copies, discussing or rencing the subjects of this litigation including the pelvic mesh product(s), the ries and/or damages you claim resulted from the pelvic mesh product(s), or encing your physical condition from three years prior to the implantation of pelvic mesh product(s) to present, including but not limited to the injuries for the you claim relief in this lawsuit. Research conducted to understand the legal strategic advice of your counsel is not considered responsive to this request.				
	i.	Not Applicable				
	ii.	The documents are attached [OR] I have no documents				
e)	Produce any pelvic mesh product packaging, labeling, advertising, or any other pelvic mesh product product-related items in your possession, custody or control.					
	i.	Not Applicable				
	ii.	The documents are attached [OR] I have no documents				
f)	and Defe	duce all documents concerning any communication between you and the Food Drug Administration (FDA) or between you and any employee or agent of the endants, regarding the pelvic mesh product(s) at issue, except as to those munications which are attorney client/work product privileged.				
	i.	Not Applicable				
	ii.	The documents are attached [OR] I have no documents				
g)	to ar	luce all documents in your possession, custody or control evidencing or relating my correspondence or communication between either you or Coloplast Corp., any of its related companies or divisions) with any of your doctors, healthcare				

communications which are attorney client/work product privileged.

providers, and/or you relating to the pelvic mesh product(s), except as to those

	i.	Not Applicable					
	ii.	The documents are attached [OR] I have no documents					
h)	desc to in of ye	duce any and all documents in your possession, custody or control reflecting, ribing, or in any way relating to any instructions or warnings you received prior applantation of any pelvic mesh product(s) concerning the risks and/or benefits our surgery, including but not limited to any risks and/or benefits associated the pelvic mesh product(s).					
	i.	Not Applicable					
	ii.	The documents are attached [OR] I have no documents					
i)		luce any and all documents reflecting the model number and lot number of the ic mesh product(s) you received.					
	i.	Not Applicable					
	ii.	The documents are attached [OR] I have no documents					
j)	that cont your	ou underwent surgery to explant in whole or in part the pelvic mesh product(s) you received: produce any and all documents in your possession, custody or rol aside from documents that may have been generated by experts retained by counsel for litigation purposes, relating to any evaluation of the pelvic mesh uct(s) and any other material that was (were) surgically removed from you.					
	i.	Not Applicable					
	ii.	The documents are attached [OR] I have no documents					
k)	_	ou claim lost wages or lost earning capacity, copies of your federal and state tax rns for the two years prior to implantation of the pelvic mesh product(s) to the ent.					
	i.	Not Applicable					
	ii.	The documents are attached [OR] I have no documents					
	•	If you do not have the required tax returns, you must provide fully completed authorizations for the release of federal and state tax returns.					
1)		documents in your possession, custody or control concerning payment by icare on the injured party's behalf relating to the injuries claimed in this lawsuit,					

including but not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on

V	our	behalf	for	medical	expenses	relating to	the s	subject	of this	litigation
J										. 6

i.	Not Applicable		
ii.	The documents are attached	[OR] I have no documents	

[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 at that time. 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.]

VERIFICATION

I,	, declare under penalty of perjury subject to all
applicable laws, that I have carefu	illy reviewed the final copy of this Plaintiff Fact Sheet dated
and verified that all c	of the information provided is true and correct to the best of my
knowledge, information and belief.	
	Signature of Plaintiff
<u>VERIFICA</u>	TION OF LOSS OF CONSORTIUM
Ι,	, declare under penalty of perjury subject to all
applicable laws, that I have carefu	illy reviewed the final copy of this Plaintiff Fact Sheet dated
and verified that all of	f the information provided is true and correct to the best of my
knowledge, information and belief.	
	Signature of Consortium Plaintiff

APPENDIX "A"

(Authorization Forms)

Instructions for Using this Form

Complete this form only if you want us to give information or records about you, a minor, or a legally incompetent adult, to an individual or group (for example, a doctor or an insurance company). If you are the natural or adoptive parent or legal guardian, acting on behalf of a minor child, you may complete this form to release only the minor's non-medical records. We may charge a fee for providing information unrelated to the administration of a program under the Social Security Act.

NOTE: Do not use this form to:

- Request the release of medical records on behalf of a minor child. Instead, visit your local Social Security office or call our toll-free number, 1-800-772-1213 (TTY-1-800-325-0778), or
- Request detailed information about your earnings or employment history. Instead, complete and mail form SSA-7050-F4. You can obtain form SSA-7050-F4 from your local Social Security office or online at www.ssa.gov/online/ssa-7050.pdf.

How to Complete this Form

We will not honor this form unless all required fields are completed. An asterisk (*) indicates a required field. Also, we will not honor blanket requests for "any and all records" or the "entire file." You must specify the information you are requesting and you must sign and date this form. We may charge a fee to release information for non-program purposes.

- Fill in your name, date of birth, and social security number or the name, date of birth, and social security number of the person to whom the requested information pertains.
- Fill in the name and address of the person or organization where you want us to send the requested information.
- Specify the reason you want us to release the information.
- Check the box next to the type(s) of information you want us to release including the date ranges, where applicable.
- You, the parent or the legal guardian acting on behalf of a minor child or legally incompetent adult, must sign and date this form and provide a daytime phone number.
- If you are not the individual to whom the requested information pertains, state your relationship to that person. We may require proof of relationship.

PRIVACY ACT STATEMENT

Section 205(a) of the Social Security Act, as amended, authorizes us to collect the information requested on this form. We will use the information you provide to respond to your request for access to the records we maintain about you or to process your request to release your records to a third party. You do not have to provide the requested information. Your response is voluntary; however, we cannot honor your request to release information or records about you to another person or organization without your consent. We rarely use the information provided on this form for any purpose other than to respond to requests for SSA records information. However, the Privacy Act (5 U.S.C. § 552a(b)) permits us to disclose the information you provide on this form in accordance with approved routine uses, which include but are not limited to the following:

- 1.To enable an agency or third party to assist Social Security in establishing rights to Social Security benefits and or coverage;
- 2.To make determinations for eligibility in similar health and income maintenance programs at the Federal, State, and local level;
- 3.To comply with Federal laws requiring the disclosure of the information from our records; and,
- 4.To facilitate statistical research, audit, or investigative activities necessary to assure the integrity of SSA programs.

We may also use the information you provide when we match records by computer. Computer matching programs compare our records with those of other Federal, State, or local government agencies. We use information from these matching programs to establish or verify a person's eligibility for Federally-funded or administered benefit programs and for repayment of incorrect payments or overpayments under these programs. Additional information regarding this form, routine uses of information, and other Social Security programs is available on our Internet website, www.socialsecurity.gov, or at your local Social Security office.

PAPERWORK REDUCTION ACT STATEMENT

This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the <u>Paperwork Reduction</u> <u>Act of 1995.</u> You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 3 minutes to read the instructions, gather the facts, and answer the questions. **SEND OR BRING THE COMPLETED FORM TO YOUR LOCAL SOCIAL SECURITY OFFICE.** You can find your local Social Security office through SSA's website at <u>www.socialsecurity.gov.</u> Offices are also listed under U.S. Government agencies in your telephone directory or you may call 1-800-772-1213 (TYY 1-800-325-0778). You may send comments on our time estimate above to: SSA, 6401 Security Blvd., Baltimore, MD 21235-6401. Send <u>only</u> comments relating to our time estimate to this address, not the completed form.

Consent for Release of Information

You must complete all required fields. We will not honor your request unless all required fields are completed. (*signifies a required field).

TO: Social Security Administration *My Full Name *My Social Security Number *My Date of Birth (MM/DD/YYYY) I authorize the Social Security Administration to release information or records about me to: *NAME OF PERSON OR ORGANIZATION: *ADDRESS OF PERSON OR ORGANIZATION: *I want this information released because: We may charge a fee to release information for non-program purposes. *Please release the following information selected from the list below: You must specify the records you are requesting by checking at least one box. We will not honor a request for "any and all records" or "my entire file." Also, we will not disclose records unless you include the applicable date ranges where requested. 1. Social Security Number 2. Current monthly Social Security benefit amount 3. Current monthly Supplemental Security Income payment amount 4. My benefit or payment amounts from date ______ to date _____ 5. My Medicare entitlement from date ______ to date _____ 6. Medical records from my claims folder(s) from date to date If you want us to release a minor child's medical records, do not use this form. Instead, contact your local Social Security office. 7. Complete medical records from my claims folder(s) 8. Other record(s) from my file (you must specify the records you are requesting, e.g., doctor report, application, determination or questionnaire) I am the individual, to whom the requested information or record applies, or the parent or legal guardian of a minor, or the legal guardian of a legally incompetent adult. I declare under penalty of perjury (28 CFR § 16.41(d)(2004)) that I have examined all the information on this form, and any accompanying statements or forms, and it is true and correct to the best of my knowledge. I understand that anyone who knowingly or willfully seeks or obtain access to records about another person under false pretenses is punishable by a fine of up to \$5,000. I also understand that I must pay all applicable fees for requesting information for a non-program-related purpose. *Signature: *Date: *Address: *Daytime Phone: Relationship (if not the subject of the record): Witnesses must sign this form ONLY if the above signature is by mark (X). If signed by mark (X), two witnesses to the signing who know the signee must sign below and provide their full addresses. Please print the signee's name next to the mark (X) on the signature line above. 1.Signature of witness 2. Signature of witness Address(Number and street, City, State, and Zip Code) Address(Number and street, City, State, and Zip Code)





Beneficiary Services:1-800-MEDICARE (1-800-633-4227) TTY/TDD:1-877-486-2048

This form is used to advise Medicare of the person or persons you have chosen to have access to your personal health information.

Where to Return Your Completed Authorization Forms:

After you complete and sign the authorization form, return it to the address below:

Medicare BCC, Written Authorization Dept. PO Box 1270 Lawrence, KS 66044

For New York Medicare Beneficiaries ONLY

The New York State Public Health Law protects information that reasonably could identify someone as having HIV symptoms or infection, and information regarding a person's contacts. Because of New York's laws protecting the privacy of information related to alcohol and drug abuse, mental health treatment, and HIV, there are special instructions for how you, as a New York resident, should complete this form.

- For question 2A, check the box for *Limited Information*, even if you want to authorize Medicare to release any and all of your personal health information.
- Then proceed to question 2B. You may also check any of the remaining boxes and include any additional limitations in the space provided. For example, you could write "payment information".

Instructions for Completing Section 2C of the Authorization Form:

Please select one of the following options.

- Option 1 To include all information, check the box: "all information, including information about alcohol and drug abuse, mental health treatment, and HIV". Proceed with the rest of the form.
- Option 2 To exclude the information listed above, check the box: "Exclude information about alcohol and drug abuse, mental health treatment and HIV". Then proceed with the rest of the form.

If you have any questions or need additional assistance, please feel free to call us at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Sincerely,

1-800-MEDICARE Customer Service Representative

Encl.

Information to Help You Fill Out the "1-800-MEDICARE Authorization to Disclose Personal Health Information" Form

By law, Medicare must have your written permission (an "authorization") to use or give out your personal medical information for any purpose that isn't set out in the privacy notice contained in the Medicare & You handbook. You may take back ("revoke") your written permission at any time, except if Medicare has already acted based on your permission.

If you want 1-800-MEDICARE to give your personal health information to someone other than you, you need to let Medicare know in writing.

If you are requesting personal health information for a deceased beneficiary, please include a copy of the legal documentation which indicates your authority to make a request for information. (For example: Executor/Executrix papers, next of kin attested by court documents with a court stamp and a judge's signature, a Letter of Testamentary or Administration with a court stamp and judge's signature, or personal representative papers with a court stamp and judge's signature.) Also, please explain your relationship to the beneficiary.

Please use this step by step instruction sheet when completing your "1-800-MEDICARE Authorization to Disclose Personal Health Information" Form. Be sure to complete all sections of the form to ensure timely processing.

1. Print the name of the person with Medicare.

Print the Medicare number exactly as it is shown on the red, white, and blue Medicare card, including any letters (for example, 000000000A).

Print the birthday in month, day, and year (mm/dd/yyyy) of the person with Medicare.

- 2. This section tells Medicare what personal health information to give out. Please check a box in 2A to indicate how much information Medicare can disclose. If you only want Medicare to give out limited information (for example, Medicare eligibility), also check the box(es) in 2B that apply to the type of information you want Medicare to give out. Box 2C must be completed by **New York Residents**.
- 3. This section tells Medicare when to start and/or when to stop giving out your personal health information. Check the box that applies and fill in dates, if necessary.
- **4.** Medicare will give your personal health information to the person(s) or organization(s) you fill in here. You may fill in more than one person or organization.

If you designate an organization, you must also identify one or more individuals in that organization to whom Medicare may disclose your personal health information.

- 5. The person with Medicare or personal representative must sign their name, fill in the date, and provide the phone number and address of the person with Medicare.
 - If you are a personal representative of the person with Medicare, check the box, provide your address and phone number, and attach a copy of the paperwork that shows you can act for that person (for example, Power of Attorney).
- **6.** Send your completed, signed authorization to Medicare at the address shown here on your authorization form.
- 7. If you change your mind and don't want Medicare to give out your personal health information, write to the address shown under number six on the authorization form and tell Medicare. Your letter will revoke your authorization and Medicare will no longer give out your personal health information (except for the personal health information Medicare has already given out based on your permission).

You should make a copy of your signed authorization for your records before mailing it to Medicare.

1.

2.

1-800-MEDICARE Authorization to Disclose Personal Health Information

Print Name (First and last name of the person with Medicare)		Medicare Number (Exactly as shown on the Medicare Card)	Date of Birth (mm/dd/yyyy)
Medicare	will only disclose the personal healt	h information you want disclosed.	
	heck only <u>one</u> box below to tell Me isclosed:	edicare the specific personal health inf	ormation you
	Limited Information (go to question	2b)	
	Any Information (go to question 3)		
2B: Co	omplete <u>only</u> if you selected "limit	ed information". Check all that apply	:
	Information about your Medicare el	igibility	
	Information about your Medicare cla	aims	
	Information about plan enrollment (e.g. drug or MA Plan)	
	Information about premium paymen	ts	
	Other Specific Information (please v	vrite below; for example, payment infor	mation)

Exclude information about alcohol and drug abuse, mental health treatment, and HIV.

Form CMS-10106 (Rev 07/15)

OR

(mm/dd/yyyy)
Medicare to e person for lividuals or
78701
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Note: You have the right to take back ("revoke") your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. To revoke authorization, send a written request to the address noted below. Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.

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Attorney). This or
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6. Send the completed, signed authorization to:

Medicare BCC, Written Authorization Dept. PO Box 1270 Lawrence, KS 66044

PrintForm

Note: You have the right to take back ("revoke") your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. If you would like to revoke authorization, send a written request to the address noted above.

Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0930. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: COLOPLAST CORP., PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO

Civil Action No.:________

Name of Plaintiff

DEFENDANT FACT SHEET

For each case involving a Coloplast product, Defendant Coloplast Corp. (hereinafter "Coloplast" or "Defendant") shall produce any non-privileged matter that is relevant to the request pursuant to Rule 26(b) of the Federal Rules of Civil Procedure. Except as otherwise set forth in any Order, this Fact Sheet must be completed and served on Plaintiffs' counsel in each individual case by ______.

I. INFORMATION

Case Caption:	 	
Case Number:	 	

II. IMPLANTING AND EVALUATING PHYSICIANS

Plaintiff has identified physicians in Sections II.1 ("Implanting Physician") and II.6.f. of the Plaintiff's Fact Sheet (together, "Identified Physicians"). As to each Identified Physician, provide or produce the following information:

A. NON-SALES REPRESENTATIVE CONSULTATION CONTACTS

As to each Identified Physician with whom the Defendant was affiliated or consulted regarding the female pelvic mesh product(s) (outside the context of sales representative contacts), Defendant will provide the following for each Identified Physician:

- 1. Identify the Identified Physician.
- 2. Any communications between the Defendant and the Identified Physician relevant to Defendant's female pelvic mesh product(s), including communications regarding the safety, use, or efficacy of Defendant's female pelvic mesh products.

Exhibit B

- 3. Any monetary or non-monetary benefits provided to the Identified Physician by the Defendant.
- 4. Written agreements, including contracts, setting forth the terms or nature of any consultation or affiliation with the Identified Physician related to Defendant's female pelvic mesh product(s); this includes but is not limited to any contracts to research or otherwise study Defendant's female pelvic mesh product(s).
- 5. For each facility identified by the Plaintiff as one in which she had a surgical implant of Defendant's product by the Implanting Physician, set forth the number and type of women's pelvic mesh product(s) purchased from Defendant for five (5) years prior to the date of surgery.
- 6. Set forth any communication between the Defendant and the Identified Physician with regard to the Plaintiff.

B. <u>SALES REPRESENTATIVES</u>

For each Implanting Physician identified by Plaintiff in the Plaintiff Fact Sheet, set forth the following or produce relevant, non-privileged documents:

- 1. Identify the Implanting Physician.
- 2. Identity of Defendant's sales representative(s), if any, that have had contact with the Implanting Physician regarding Defendant's female pelvic mesh product(s).
- 3. State whether or not the Defendant's sales representative(s) identified above is currently employed by Defendant. If the sales representative(s) is no longer employed by Defendant, please provide the last known address of the sales representative(s).
- 4. The name and model number for the female pelvic mesh product(s) that the sales representative was responsible for with regard to the Implanting Physician.
- 5. Identify all district and/or regional sales managers who were responsible for the management of the sales representatives identified in your response to Number 2 above, and their current relationship, if any, with Defendant.
- 6. Set forth all information related to the use of Defendant's female pelvic mesh product(s) provided by the physician to the sales representative, with regard to the Plaintiff.
- 7. Identify any reprimand or rebuke for any non-privileged relevant reason of the sales representative while employed by you.

Exhibit B

III. INFORMATION REGARDING THE PLAINTIFF

- A. Outside of information exchanged as part of this litigation, identify all data, information, objects, and reports in Defendant's possession or control specific to the Plaintiff. Attorney-work product is specifically excluded.
- B. Identify any contact, either written or oral, between the Plaintiff and any employee or representative of the Defendant, including but not limited to pre-operative inquiries, and post-operative complaints. This request specifically includes, but is not limited to, calls to your Customer Care Center.
- C. Identify all Med Watch Adverse Event Reports and/or any other documents submitted to the FDA or any other government agency with regard to the Plaintiff.
- D. If Plaintiff has provided a lot number for Defendant's product in Section II.1 of the Plaintiff's Fact Sheet, state whether such lot number has ever been subject to a recall.
- E. Identify all communications that Defendant has had with any of the Plaintiff's Identified Physicians specifically regarding the Plaintiff.
- F. If you have any evidence or records indicating or demonstrating the possibility that any person, entity, condition, or product, other than the Defendant and its product(s), is a cause of the Plaintiff's injuries, ("Alternate Cause") set forth:
 - 1. Identify the Alternate Cause with specificity.
 - 2. Set forth the date and mechanism of alternate causation.

IV. MANUFACTURING INFORMATION

- A. With respect to any Defendant's female pelvic mesh product implanted in the Plaintiff and which is the subject of this suit (where Plaintiff has provided a lot number for Defendant's product in Section II.1 of the Plaintiff's Fact Sheet), identify the device history record.
- B. Where Plaintiff has provided a lot number for Defendant's product in Section II.1 of the Plaintiff's Fact Sheet and has identified the implanting facility, identify the date of order, invoicing and shipping, and the person or entity purchasing, for each of Plaintiff's implanted device(s).
- C. Identify manufacturers of Defendant's female pelvic mesh devices

implanted in the Plaintiff.

V. DOCUMENTS

Please provide the following documents pursuant to an ESI protocol to be agreed upon by the parties or entered by the Court.

- A. The specific documentation described in I through IV above; except you need not serve copies of medical records that were provided to Defendant by Plaintiff's counsel.
- B. The specific documentation described in section II above; except you need not serve copies of medical records that were provided to Defendant by Plaintiff's counsel.
- C. The specific documentation described in section III above; except you need not serve copies of medical records that were provided to Defendant by Plaintiff's counsel.
- D. The specific documentation described in section IV above; except you need not serve copies of medical records that were provided to Defendant by Plaintiff's counsel.
- E. Aside from any privileged or attorney-work product materials, produce all documents that refer, reference, attribute, or allude to to the Plaintiff in Defendant's possession or control, to the extent not identified and attached in response to a prior question.
- F. For a lot number identified by Plaintiff in Section II.1 of Plaintiff's Fact Sheet, produce a true and complete copy of the device history record.
- G. Produce a true and complete copy of the complaint file relating to the Plaintiff.
- H. All call notes, details notes, or call summaries made by Defendant's sales representatives regarding each Identified Physician relating to Defendant's female pelvic mesh product(s) during the relevant time period.
- I. Any communications between Defendant or its sales representatives and the Identified Physician regarding Defendant's female pelvic mesh product(s).

VERIFICATION

I am an authorized agent of Coloplast and I verify the Defendant's Response to Defendant's Fact Sheet in *In Re Coloplast Corp.*, *Pelvic Support Systems Products Liability Litigation*, MDL No. 2387 (S.D. W. Va.). The matters stated therein are not my personal knowledge; the facts stated herein have been assembled by authorized employees and counsel of Coloplast Corp. and I am informed that the facts stated herein are true. I hereby certify, in my authorized capacity as an agent for Coloplast Corp., that the responses to the aforementioned Defendant's Fact Sheet are true and complete to the best of Coloplast Corp.'s knowledge.

Date:	
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