AMS TVM Class Action c/o RicePoint Administration Inc. P.O. Box 4454, Toronto Station A 25 The Esplanade Toronto, ON M5W 4B1

**TRQ** 

AMS TVM CLASS ACTION

Must Be Postmarked No Later Than July 27, 2022

# **Claim Form - Supplemental Claims Period**

# AMERICAN MEDICAL SYSTEMS WOMEN'S PELVIC MESH CLASS ACTIONS SETTLEMENT INSTRUCTIONS FOR CLAIMANTS

American Medical Systems pelvic mesh devices are used to treat either stress urinary incontinence ("SUI") or pelvic organ prolapse ("POP"). To be eligible to make a claim, you must be resident in Canada and implanted with an AMS Women's Pelvic Mesh Product on or before June 25, 2019.

For the purposes of this Claim Form, "AMS Women's Pelvic Mesh Device" means any of the products listed below. If you have more than one of the below listed products, you may claim in respect of each one.

Stress Urinary Incontinence Products: means each of SPARC® (including, but not limited to, SPARC® Sling System), BioArc® (including, but not limited to, BioArc® TO Sling Kit, BioArc® TO System with InteXen® LP, BioArc® SP Sling Kit and BioArc® SP System with InteXen® LP), Monarc® (including, but not limited to, Monarc® Subfascial Hammock, Monarc® C Subfascial Hammock and Monarc® + Subfascial Hammock), MiniArc® (including, but not limited to, MiniArc® Single-Incision Sling System, MiniArc® Precise™ Single-Incision Sling System, and MiniArc® Pro™ Single-Incision Sling System), In-Fast® (including, but not limited to, In-Fast® Bone Screw System, In-Fast Ultra® Bone Screw System, In-Fast® Sling System, In-Fast Ultra® Sling System and In-Fast® with Influence-TRG Gelseal) and RetroArc™ (including, but not limited to, RetroArc™ Retropubic Sling System).

Pelvic Organ Prolapse Products: means each of Apogee® (including, but not limited to, Apogee® Vault Suspension System, Apogee® System with Cape, Apogee® System with Bio-Cape, Apogee® Enhanced, Apogee® System with IntePro®, Apogee® System with IntePro® Lite, and Apogee® System with InteXen® LP), Elevate® (including, but not limited to, Elevate® Apical and Posterior Prolapse Repair System with IntePro® Lite, Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP, Elevate® Anterior & Apical Prolapse Repair System with InteXen® LP, Elevate® PC Apical & Posterior Prolapse Repair System, and Elevate® PC Anterior & Apical Prolapse Repair System), and Perigee® (including, but not limited to, Perigee® System, Perigee® System with IntePro®, Perigee® System with Biologic InteGraft, Perigee® Enhanced, Perigee® System with IntePro® Lite, Perigee® Plus, Perigee® Plus with IntePro® Lite and Perigee® System with InteXen® LP).

**Other:** Straight-In Sacral Colpopexy System, InteMesh Silicone-coated sling/silicone-coated surgical mesh with or without InhibiZone, InteXen Porcine Dermal Matrix, IntePro Large pore Polypropylene Y mesh and Triangle.

THE DEADLINE TO SUBMIT A CLAIM IS JULY 27, 2022.



Claim Forms can be submitted to the Claims Administrator online at <u>www.amsmeshclassactions.ca</u>. For claims submitted in paper form, Claim Forms must be postmarked on or before July 27, 2022 and mailed to the following address:

AMS TVM Class Action c/o RicePoint Administration Inc. P.O. Box 4454, Toronto Station A 25 The Esplanade Toronto, ON M5W 4B1

If you require assistance or advice regarding completion of the Claim Form, you may retain legal counsel at your own expense or contact the Claims Administrator, free of charge, at 1-866-571-7804. Claimants who retain lawyers or agents in completing their Claim Form shall be solely responsible for the fees and expenses of such lawyers or agents.

Claimants (or their lawyers/agents) **must** advise the Claims Administrator **in writing** of any changes or corrections in name, address, phone number, or legal representation.

Please keep copies of all documentation you send to the Claims Administrator.

Please note that it could take several weeks or longer to obtain the required supporting medical documentation to support your claim. Please start completing the claims process now.

If you are claiming on behalf of an Estate or a person with a disability, you must provide all supporting documents that authorize you to represent the Estate or person under disability.

#### PRIVACY STATEMENT

Personal Information regarding Claimants is collected, used and retained by the Claims Administrator pursuant to the *Personal Information Protection and Electronics Documents Act*, S.C. 2000, c.5 (PIPEDA):

- for the purpose of operating and administering the American Medical Systems Women's Pelvic Mesh Settlement ("Settlement");
- to evaluate and consider the Claimant's eligibility under the Settlement; and
- is strictly private and confidential and will not be disclosed without the express written consent of the Claimant except as provided for in the Settlement and Compensation Protocol.



### AMS WOMEN'S PELVIC MESH CLASS ACTIONS SETTLEMENT CLAIM FORM

## **SECTION 1 - Claimant Identification**

I	am applying	on	behalf	of the	follov	ving	Claimant:

<ol> <li>Myself</li> <li>Claimant A or B:</li> <li>A. A person under legal disability</li> </ol>					
Please enclose a copy of your authority to act (i.e. power  B. Deceased  Please enclose a copy of your authority to act (i.e. will, co					
If you submitted a claim in the Initial Claims period, please provide your claim ID.  TRQ-					
	ho is over the age of 18. If you are applying on behalf of an individual te Section 2. If you are a lawyer or agent who is completing this form				
Claimant's First Name M.I.	Last Name				
Address					
City	Province Postal Code				
Llama Phana	Work Phone				
Home Phone	Work Phone				
Email					
Liliaii					
Provincial Health Card Number					
MM/DD/YYYY Date of Birth					
M M / D D / Y Y Y Y  For Estate Claims: Date of Death					



<sup>\*</sup>Please attach the official death certificate.

### **SECTION 2 - Representative Identification**

This section is to be completed <u>only</u> if you are submitting a claim as the Representative of an individual under legal disability or an Estate. You MUST provide proof of your authority to act as the Representative of an individual under legal disability or an Estate.

Representative's First Name	M.I.	Last Name
Address		
City		Province Postal Code
Home Phone		Work Phone
Email		
Specify proof of authority to represent provided:		

### **SECTION 3 - Legal Representative Identification**

This Section is to be completed only if a lawyer or agent is representing the Claimant, Estate Representative or Representative of an individual under legal disability. If you complete this section, all correspondence will be sent to your legal representative. If you complete this section, you MUST complete Schedule "A".

Name of Law Firm or Agency				
Lawyer's or Agent's First Name	M.I.	Last Name		
Address				
City			Province	Postal Code
Phone				
Email				



## **SECTION 4 - Initial Implant Supporting Information**

Please complete the chart below for each AMS women's pelvic mesh product implanted. **Do NOT include information on mesh products manufactured by other companies.** 

Implant #1		
Implant Name/Model		
Date of Implant		
Pre-Operative Diagnosis		
Post-Operative Diagnosis		
Operative Procedure Performed		
Facility/Physician		
	Implant #2	
Implant Name/Model		
Date of Implant		
Pre-Operative Diagnosis		
Post-Operative Diagnosis		
Operative Procedure Performed		
Facility/Physician		
	Implant #3	
Implant Name/Model	Implant #3	
Implant Name/Model  Date of Implant	Implant #3	
	Implant #3	
Date of Implant	Implant #3	
Date of Implant Pre-Operative Diagnosis	Implant #3	
Date of Implant Pre-Operative Diagnosis	Implant #3	
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis	Implant #3	
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis	Implant #3	
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis Operative Procedure Performed	Implant #3  Implant #4	
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis Operative Procedure Performed		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis Operative Procedure Performed Facility/Physician		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis  Operative Procedure Performed  Facility/Physician  Implant Name/Model		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis Operative Procedure Performed Facility/Physician Implant Name/Model Date of Implant		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis  Operative Procedure Performed  Facility/Physician  Implant Name/Model Date of Implant Pre-Operative Diagnosis		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis  Operative Procedure Performed  Facility/Physician  Implant Name/Model Date of Implant Pre-Operative Diagnosis		
Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis  Operative Procedure Performed  Facility/Physician  Implant Name/Model Date of Implant Pre-Operative Diagnosis Post-Operative Diagnosis		



Note: See Page 1 for a list of eligible AMS Women's Pelvic Mesh Device products. To be eligible for compensation under this Settlement, for EACH AMS Women's Pelvic Mesh Device implanted, you MUST provide:

A copy of the product identification sticker(s) (PID)

OR if a copy or copies of the PID is/are not available and the implant is an AMS Women's Pelvic Mesh Device, you must submit one or more of the other forms of evidence below:

- Medical records contemporaneous to the implantation procedure for the AMS Women's Pelvic Mesh Device recording the product identification information (product numbers) from the product identification sticker, tag, or label;
- Medical records contemporaneous to the implantation procedure for the AMS Women's Pelvic Mesh Device identifying the information of the model of the AMS Women's Pelvic Mesh Device;
- Documentation from the implanting surgeon providing confirmation of the <u>model</u> of the AMS Women's Pelvic Mesh Device OR other confirmation that the implanted device was an AMS Women's Pelvic Mesh Device; or
- Documentation from the implanting hospital purchasing department providing confirmation of the <u>model</u> of the AMS Women's Pelvic Mesh Device OR other confirmation that the implanted device was an AMS Women's Pelvic Mesh Device.

For implanted mesh products made by ANOTHER manufacturer, please provide product documentation if you have it. <u>SECTION 5 - Qualifying Treatment and Supporting Surgical or Treatment Evidence</u>

Please check all that apply and provide the required medical evidence. Note: medical records supporting each category are required to be eligible for compensation.

Treatment	Supporting Treatment Evidence	Approximate Date(s) of Treatment
Please indicate all treatments below which were performed AFTER implantation of your AMS Women's Pelvic Mesh Device that are attributed by your treating medical provider to your complications/symptoms from the implantation of your AMS Women's Pelvic Mesh Device.	For the purposes of this Claim Form, "Surgical or Treatment Evidence" means proof, by way of contemporaneous medical records, which may include contemporaneous physician or hospital records supplemented by a letter from the physician providing any needed clarification of the contents of the records, of each claimed surgical intervention or treatment which is used to claim compensation.  Please select all that apply and for which medical records are included with this claim.	
Pain medications for treatment of pelvic pain	Medical evidence confirming a prescription for pain medication for treatment of pelvic pain commencing at least 90 days after implantation of an AMS Women's Pelvic Mesh Device and with continuous use for a period of at least two months is included and attached.  Note: Surgical Pain is a normal outcome of a surgical procedure and is not compensable under this Settlement.	



Treatment	Supporting Treatment Evidence	Approximate Date(s) of Treatment
Physical therapy of pelvic floor and/or vaginal area  Start Date:  Stop Date:  Number of Sessions:	Evidence of physical therapy of pelvic floor and/ or vaginal area commencing at least 90 days after implantation of an AMS Women's Pelvic Mesh Device and involving at least 4 sessions over a 60-day period, is included and attached.	
Anesthetic block (e.g. epidural, spinal) for pain in or originating from the pelvic area	Medical evidence of anesthetic block (e.g. epidural, spinal) for pain in or originating from the pelvic area is included and attached.	
Either of trigger point injection, local nerve block or nerve ablation in the pelvic area	Medical evidence of trigger point injection and/ or local nerve block and/or nerve ablation in the pelvic area is included and attached.	
Botox injection(s) into pelvic muscles	Medical evidence of Botox injection(s) into the pelvic muscle is included and attached.	
Revision and/or trim of an AMS Women's Pelvic Mesh Device under topical or local anesthetic	Medical evidence of revision and/or trim of an AMS Women's Pelvic Mesh Device under topical or local anesthetic is included and attached.	
Drainage of sinus tract or abscess occurring within the vicinity of site implant or insertion tract	Medical evidence of drainage of sinus tract or abscess occurring within the vicinity of the site of implantation or the insertion tract of an AMS Women's Pelvic Mesh Device, and which was performed at least 30 days after the implantation of an AMS Women's Pelvic Mesh Device, is included and attached.	
3 or more bacterial infections (vaginal or urinary tract) treated with antibiotics	Medical evidence of 3 or more bacterial infections (vaginal or urinary tract) treated with antibiotics at least 30 days after the implantation of an AMS Women's Pelvic Mesh Device, is included and attached.	



Treatment		Supporting Treatment Evidence	Approximate Date(s) of Treatment
related treatments or rel new-onset mesh related co		edical evidence of other non-surgical mesh lated treatments or new-onset mesh related enditions (i.e. fistula, and organ (i.e. bladder or owel perforation)) is included and attached.	
Describe:			
Qualifying Surgery		Supporting Surgical Evidence	Approximate Date(s) of Surgery
Defined as a Surgical Procedure performed under General Anesthesia or Regional Anesthesia to:		Please complete all boxes for which Surgical Treatment Evidence is provided with this Claim Form. Operative Reports and Medical Records are required for each procedure claimed.	
Remove all or a portion of an AMS Women's Pelvic Mesh Device		Surgical records confirming removal of all or a portion of an AMS Women's Pelvic Mesh Device are included and attached.	
Release the arms of an AMS Women's Pelvic Mesh Device		Surgical records confirming release of the arms of an AMS Women's Pelvic Mesh Device are included and attached.	
Excise or lyse scar tissue or scar bands at the site of implant of an AMS Women's Pelvic Mesh Device		Surgical records confirming excise or lyse scar tissue or scar bands at site of implant of an AMS Women's Pelvic Mesh Device are included and attached.	



Qualifying Surgery	Supporting Surgical Evidence	Approximate Date(s) of Surgery		
Explore the cause of a condition or symptom suspected by the treating medical provider(s) in the contemporaneous medical records to be caused by the implantation of an AMS Women's Pelvic Mesh Device, which is performed via an open or laparoscopic approach, and for which the operative records do not reflect that another cause of the condition or symptom (e.g., ovarian cyst, endometriosis) was determined as the cause during surgery.	Surgical records confirming the exploration of the cause of a condition or symptom to be caused by the implantation of an AMS Women's Pelvic Mesh Device, which is performed via an open or laparoscopic approach, and for which the operative records do not reflect that another cause of the condition or symptom (e.g., ovarian cyst, endometriosis) was determined as the cause during surgery, are included and attached.			
SECTION 6 - Release of Claims				
I verify that I have / have not received compensation through other proceedings or private out-of-class settlements and/or provided a release in respect of an AMS Women's Pelvic Mesh Device.				
If you have received compensation or released claims, please provide the details here:				
Compensation: \$				
Details of Claims Released:				



#### **SECTION 7 - Claimant Declaration and Authorization**

The undersigned hereby consents to the disclosure of the information contained herein to the extent necessary to process this claim for benefits. The undersigned acknowledges and understands that this Claim Form is an official Court document sanctioned by the Court that presides over the Settlement, and submitting this Claim Form to the Claims Administrator is equivalent to filing it with a Court.

The undersigned hereby authorizes the Claims Administrator to contact the Claimant as required in order to administer the claim.

I verify that I am at least 18 years old.

After reviewing the information that has been supplied on this Claim Form, the undersigned declares under penalty of perjury that the information provided in this Claim Form is true and correct to the best of his/her knowledge, information and belief.

Claimant's Signature (or Claimant's Representative):	
Printed Name of Claimant (or Claimant's Representative): _	
Dated (mm/dd/yyyy):	

#### PLEASE ATTACH AND SUBMIT ALL REQUIRED SUPPORTING EVIDENCE WITH YOUR CLAIM

#### **Reminder Checklist:**

- 1. Complete the relevant sections and sign the Declaration and Authorization
- 2. If the Claim is being submitted by a third party (lawyer or agent), please complete, sign and have Schedule "A" witnessed (anyone over the age of 18 can witness).
- 3. Keep a copy of your claim form and all supporting documentation for your records.
- 4. If you move, please send the Claims Administrator your new address. Failure to notify the Claims Administrator of a new address may result in your settlement benefits not being paid to you.



### Schedule "A"

# CLAIMS FILED BY A LEGAL REPRESENTATIVE ON BEHALF OF THE SETTLEMENT CLASS MEMBER

This Schedule is to be completed <u>only</u> if the Claim is being submitted by a third-party on behalf of the Claimant.

I,	[name of Claimant, Estate Representative or Representative
of an individual under legal disability] authorize	
[name of Legal Representative (Lawyer or Agent)] to file a Claim F	Form in the AMS Women's Pelvic Mesh Class Action on my behalf and
to receive all communication relevant to my claim (including the c	cheque, if eligible for payment).
DATED at the city of, in the Prov	vince of, in the Country of,
this day of	
Individual Claimant, Estate Representative OR R	Representative of an individual under legal disability:
Signature:	
Witness Signature:	
Witness Print Name	



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