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SCHEDULE D

Case Assessment Criteria

Quebec Class Only

Entry Level Requirements for Participation	1. Product ID or sticker confirming placement of a Coloplast medical device
	2. Claimant received their surgical mesh implant or underwent relevant medical care as documented by the medical records after *November 14, 2016*, the end of the claim period in the *Naylor v. Coloplast* class action, instituted on behalf of (a) all persons resident in Canada who have been implanted with transvaginal mesh products which were variously designed, developed, tested, manufactured, licensed, assembled, labeled, marketed, instructed for use, distributed and/or sold by the Defendant; and(b) all persons resident in Canada who by virtue of a personal relationship with one or more of such persons described in (a) above, having standing in this action pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3 or analogous provincial legislation or at common law

Tier 1 *Not eligible for inclusion in settlement class*	1. Product-in-place ("PIP"[1]) with no current adverse events
	2. Claimants with Altis, Restorelle Y, Restorelle M, Restorelle L, Restorelle XL, and Restorelle Contour, or biologic implants
	3. No post-implant medical records provided
	4. Claimants implanted with another manufacturer's surgical mesh implant(s) to treat stress urinary incontinence and/or pelvic organ

[1] By ***PIP***, we refer to "product in place" meaning that the Coloplast Device has not been explanted and no medical record of claimant indicates any medical issue directly related to the Coloplast Device.

	prolapse where either: (1) the claimant settled with the other manufacturer and there is no indication in the medical records that the Coloplast device directly contributed to the alleged injuries; or (2) the medical records demonstrate that the other surgical mesh implant(s) to treat stress urinary incontinence and/or pelvic organ prolapse directly contributed to the alleged injuries/subsequent procedures
	5. Claimants with prior pelvic surgeries that contributed to the alleged injuries/subsequent procedures as noted in the medical records
	6. Claimants whose medical records include a notation, prior to the date of surgery, from a doctor indicating that there was a robust discussion of the risks, benefits, adverse events
	7. Claimants with post-implant procedures that were never recommended by a physician and for which there are no documented complaints related to her surgical mesh implant(s) in any medical record
	8. Claimants who had exposures that were effectively treated with estrogen cream
	9. Claimants whose medical records demonstrate that the surgical technique used to place the surgical mesh directly contributed to the alleged injuries (*e.g.*, subsequent notation that the sling was placed around the bladder neck)
	10. Medical records demonstrate claimant noncompliance with postoperative instructions

	11. Post-procedure hematoma within the first week after implant and/or abscess occurring within 12 weeks after the implant procedure that was in direct relation to the alleged injuries
	12. Claimants whose alleged injuries are caused by preexisting overactive bladder
	13. Claimants whose alleged injuries are caused by preexisting interstitial cystitis
	14. Surgeon implemented poor patient selection (patient had a pre-existing history of any condition listed under the "Contraindications" section in the applicable Instructions for Use, including but not limited to pregnancy or desire for future pregnancy; known active urinary tract infection and/or infection in operative field; abnormal urethra (e.g., condition, including known or suspected pelvic pathology; sensitivity/allergy to polypropylene))

If claimant is not excluded per the criteria of Tier 1, and claimant is deemed eligible, then the following criteria is used to determine tier placement

Tier 2 *Lowest recovery range* *Up to $2,500*	1. Subsequent in-office procedure with or without local anesthetic
	2. SUI claimants with subsequently placed full-length slings to treat voiding dysfunction
	3. POP claimants with subsequently placed POP mesh to treat prolapse in different compartments

Tier 3 *Minimum recovery: $2,000* *Up to $35,000*	1. One revision procedure
	2. One revision recommended by a physician
	NOTE: A "revision," as used within this document, is defined as a subsequent surgical procedure performed in an operating room under general anesthesia or monitored anesthesia care ("MAC") (i.e., an anesthesia specialist provides care during the surgery), recommended by a physician, wherein the device was partially or completely removed. The reason for the removal must be either infection of mesh material as confirmed by pathology, documented chronic pain, or documented exposure or extrusion.
	3. Documented history of chronic pain, subsequent to the implant, treated by trigger point injections and/or nerve blocks

Tier 4 *Up to $50,000*	1. Two revision procedures, as defined above

Tier 5 *Highest recovery range* *Up to $55,000*	1. Three or more revision procedures, as defined above
	2. Extraordinary injuries (includes organ perforation by the mesh unrelated to surgical error, fistula if related to the mesh)

Factors which the special master may take into consideration in determining the value of claim within a tier range.

Each factor must have contributed to the claimant's pain or injury, and a non-contributing factor, in view of the medical evidence provided, will not be taken into account.

Each deduction is valued and deducted separately. Deductions are cumulative and there may be more than one deduction for any given claimant.

Category	Contributing Factor
Pain	Pre-existing abdominal or pelvic pain within the 5 years preceding the implant procedure
	Pre-existing dyspareunia anytime within the 5 years preceding the implant procedure
	Fibromyalgia
	Chronic pain syndrome
Tissue Quality & Healing	Smoked 1 pack per day or more for 5 years anytime within the 20 years before the implant surgery and/or smoking 1 pack per day after the implant surgery
	Untreated vaginal atrophy within the 3 months before the implant procedure and/or anytime thereafter
	Uncontrolled diabetes (hemoglobin A1C of 7% or greater 3 months before surgery or anytime moving forward)
	Uncontrolled hypertension or hypotension
Other Possible Causes of Symptoms	Diagnosis of abdominal or pelvic adhesions
	Pre-existing chronic constipation as documented in the medical records
	Irritable bowel syndrome

	Diverticulitis
	Pre-implant recurrent or chronic vaginal or bladder infections anytime within the 3 years preceding the implant procedure
	Fibroids
	Endometriosis
Other Patient Factors	Age at implant was 80 or above
	No documented preoperative diagnosis of SUI or POP (*i.e.*, preoperative diagnosis inconsistent with treatment)
	Abdominal or pelvic radiation
	Gastroenterological cancer, genitourinary cancer, or gynecological cancer
	Autoimmune conditions (*e.g.*, Crohn's disease, systemic lupus)
	Morbid obesity (BMI of 40 and above)
	Prior pregnancy(ies) that progressed to at least 30 weeks
	Previous bladder/incontinence surgery

Deduction *Deduct $22,500 from the award*	Claimant underwent a physician recommended post-implant procedure in the United States and were reimbursed by a Provincial Health Insurer