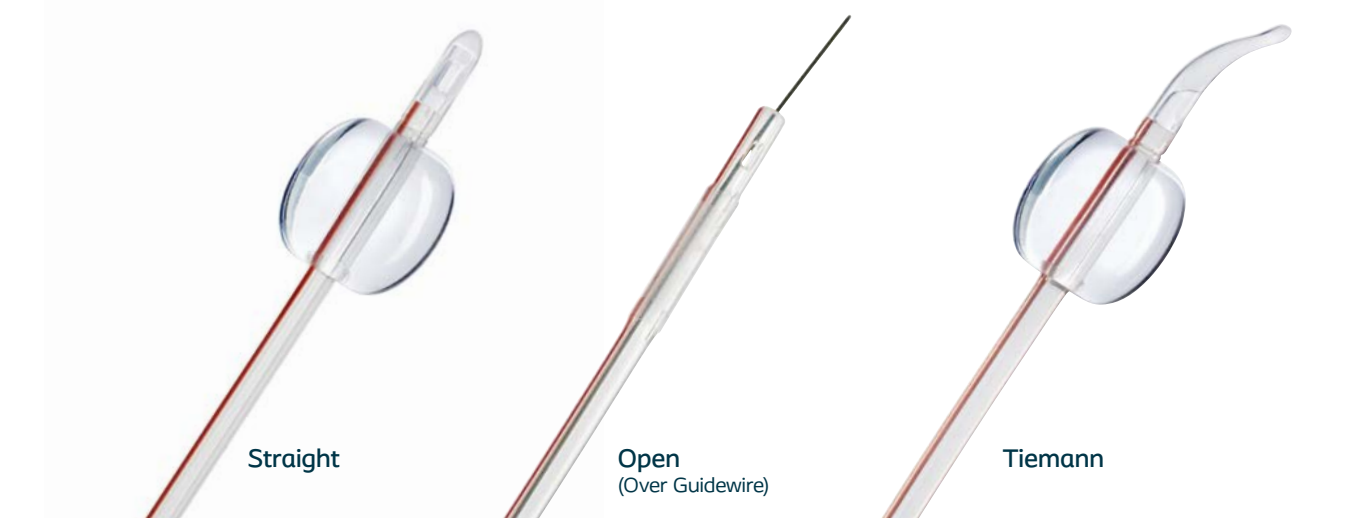


Specific design for specific needs



Folysil Catheters Brief Statement

Indications

Folysil catheters are intended for use up to 30 days in adult and pediatric populations for:

- Bladder drainage by urethral catheterization.
- Bladder drainage by suprapubic catheterization for catheter replacement only (for non-grooved, straight 2-way Folysil catheters with a maximum balloon volume of 15mL).
- Bladder instillation of physiological saline solution.

Contraindications to the medical device:

- Allergy to any component of the device.
- Do not use, if such a procedure would be contrary to the best interest of the patient, in the judgement of the physician.

Contraindications to urethral urinary catheterization

Including but not limited to:

- Urethral trauma, urethral injury, urethritis
- Complete urethral obstruction or urethral stenosis refractory to urethral insertion of the catheter
- Acute prostatitis

- Priapism
 - Presence of urethral or prostatic prosthesis
- ### Contraindications to suprapubic bladder drainage

Including but not limited to:

- Known or suspected bladder cancer
- Altered anatomy or anticipated significant adhesions (e.g. pelvic cancer, radiation, suprapubic mesh)
- Ascites, gross or morbid obesity
- Hematuria
- Uncontrolled hemostasis disorder

Warnings & Precautions

This type of device must only be used by trained and experienced professionals.

Potential Complications

The following events have been reported with Folysil catheters, although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: Vesical discomfort, pain, mucosal irritation, mucosal erosion, uro-genital trauma, urethritis, cystitis, urinary tract infection, pyelonephritis,

encrustation, stone formation, urinary retention, urine leakage, bleeding, bladder spasms, urethral perforation, urethral stricture and fistula, misplacement, false passage, displacement, reintervention, skin irritation and skin infection specially for suprapubic catheterization.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
PM-34784 / Oct 2024

Ordering Information

Coloplast Interventional Urology Service Support **800-258-3476**

Folysil® Silicone Foley Catheters

Length (cm)	Balloon (mL)	Eyes	Diameter (Ch/Fr)	Item
Male Straight				
41	10	2	12	AA6112
			14	AA6114
			16	AA6116
			18	AA6118
			20	AA6120
			22	AA6122
			24	AA6124
41	30	2	18	AA6C18
			20	AA6C20
			22	AA6C22
			24	AA6C24
Open (Over Guidewire)				
40	10	2 + tip	12	AA6412
			14	AA6414
			16	AA6416
40	15	2 + tip	18	AA6418
			20	AA6420
			22	AA6422
			24	AA6424
			Tiemann	
40	10	1	12	AA6312
			14	AA6314
40	15	1	16	AA6316
			18	AA6318
			20	AA6320
			22	AA6322
			24	AA6324

(5 EA/RB)

Folysil® Pediatric Silicone Foley Catheters

Length (cm)	Balloon (mL)	Eyes	Diameter (Ch/Fr)	Item
Pediatric Straight delivered with introducer*				
26	1.5	2	6	AA6106
26	3	2	8	AA6108
31	3	2	10	AA6110
Pediatric Tiemann delivered with introducer*				
27	3	1	8	AA6308
32	3	1	10	AA6310
Pediatric Open (Over Guidewire)				
26	3	2 + tip	8	AA6408
31	3	2 + tip	10	AA6410

(5 EA/RB)

*Pediatric catheters delivered with introducer include a stylet to facilitate urethral insertion. They therefore have a closed end.

