

The **DEFLATE** Risk Assessment: a seven-factor bedside assessment for inflated-balloon Foley pullout risk

A structured synthesis of published risk factors for unintended medical device removal.

SUMMARY

Traumatic catheter removal (TCR)—removal of an indwelling urinary catheter while the retention balloon remains inflated—is an underexamined yet common source of urethral injury. TCR typically occurs through two general mechanisms: patient-initiated self-removal, and unintended removal when tubing is caught during movement or transport. DEFLATE identifies circumstances associated with patient-initiated or unintended Foley removal while the retention balloon remains inflated, assembling seven factors drawn from the self-removal of medical devices (including Foley catheters), and unplanned extubation literature into a simple bedside assessment.

ABOUT DEFLATE

DEFLATE is a bedside assessment designed to help healthcare professionals identify adult patients with indwelling Foley catheters who may be at risk for patient-initiated or unintended catheter removal with the retention balloon inflated. It is intended to support clinical judgment and does not direct diagnosis or treatment.

TABLE 1 DEFLATE assessment factors, bedside criteria, and reported effect sizes.

FACTOR	BEDSIDE CRITERIA	REPORTED EFFECT
D Delirium or dementia	Active delirium or confusion, positive Confusion Assessment Method (CAM or CAM-ICU), sundowning, established cognitive impairment, or admission for altered mental status	Strongest independent predictor of device self-removal; OR 3.15 ¹ Late-day symptom exacerbation is well described in this population ⁷
E Extraction history	Any prior/repeat accidental or unplanned self- or staff-removal with the balloon inflated, or documented self-extubation during the current admission	Standing criterion in unplanned-removal risk screening protocols ⁴
F Fidgeting or tugging at lines	Any observed line-directed behavior—picking at securement, tracing tubing, reaching for and/or pulling at any indwelling device	Nasogastric tubes, peripheral IVs and urinary catheters are the most frequently removed devices ^{1,3}
L Lightening or Reduction of sedation	The process of sedation reduction/weaning, such as during spontaneous awakening or breathing trial, the post-extubation interval, or evening wear-off. Target range RASS -1 to +2	Lower sedation level OR 2.0–5.4; higher consciousness level OR 1.4–2.0 ²
A Agitation, restlessness or restraint	RASS ≥ +1, restlessness, undifferentiated agitation, aggression, or physical restraints already in place. Examples include traumatic brain injury, encephalopathy, alcohol, drug and nicotine withdrawal	Agitation OR 3.3–30.6; physical restraints OR 3.1; alcohol withdrawal OR 2.0; active smoking OR 3.13. ^{1,2,5} Agitation documented within 2 h before 74% of patient-initiated removals (mixed ICU devices) ⁶
T Transport and transfers	Bed-to-chair, stretcher transfers, or frequent inter-unit movement (such as for burn or soft-tissue infection patients). Mobility assistance: wheelchairs, walkers and commodes present risk	Distinct accidental mechanism; identified for heightened vigilance ³
E Emergence from anesthesia	Post-anesthesia or early post-operative patient with a catheter placed intra-operatively; tolerance not established while awake; heightened concern in patients after urologic surgery, in whom TCR can have severe consequences	Identified at-risk group in catheter self-extraction guidance ³

IMPORTANT LIMITATIONS

DEFLATE is a literature-based clinical assessment tool and has not yet been prospectively validated. Its accuracy and reliability have not been established, and most supporting evidence comes from adult ICU populations. Use in other care settings has not been evaluated.

EGRESS™ / IMPORTANT DEVICE INFORMATION

- **Indications for Use.** The Egress Safety Catheter is intended for urethral catheterization for urological bladder drainage. The device is indicated for adult use only with a maximum indwell time of no more than 30 days.
- **Rx Only.** Consult the Egress Instructions for Use for complete indications, contraindications, warnings, precautions and instructions. FDA 510(k) K241424.

REFERENCES

1. Culhane J, Okeke R, Bushe K, Freeman C. Self-removal of medical devices in the ICU: a retrospective study. *Cureus*. 2025;17(6):e86865.
2. da Silva PSL, Fonseca MCM. Unplanned endotracheal extubations in the intensive care unit: systematic review, critical appraisal, and evidence-based recommendations. *Anesth Analg*. 2012;114(5):1003–1014.
3. Prevention of inappropriate self-extraction of Foley catheters. In: *StatPearls*. Treasure Island, FL: StatPearls Publishing; 2023.
4. Decreasing unplanned extubation rates on an adult medical intensive care unit. *Crit Care Nurse*. 2026;46(4).
5. Nicotine withdrawal and agitation in ventilated critically ill patients. *Crit Care*. 2010;14(2):R58.
6. Fraser GL, Riker RR, Prato BS, Wilkins ML. The frequency and cost of patient-initiated device removal in the ICU. *Pharmacotherapy*. 2001;21(1):1–6.
7. Canevelli M, Valletta M, Trebbastoni A, et al. Sundowning in dementia: clinical relevance, pathophysiological determinants, and therapeutic approaches. *Front Med (Lausanne)*. 2016;3:73.