



## French Study (Aumeran et al., 2021) – Detailed Pathway Analysis

### Actual Pathway Breakdown

Pathway	Cases	Percentage
Endoluminal (intraluminal)	3	11.5%
Exoluminal (early – Day 1)	10	38.5%
Exoluminal (late – After Day 1)	13	50%
Total	26	100%

### Critical Comparison

Study	Intraluminal / Endoluminal Rate	Key Context
Mayo Study (1999)	34%	Approximately 10% disconnection rate
French ICU Study (2021)	11.5%	Approximately 3% disconnection rate

### Why This Matters for Spigot Guard

The French ICU study strengthens Spigot Guard's value proposition. Even under near-perfect compliance conditions (97% closed-system integrity), 11.5% of infections still occurred via the intraluminal route. These infections are potentially preventable with Spigot Guard. The Mayo study's 34% intraluminal rate reflects real-world hospital conditions, where perfect compliance is rarely achieved. At an infection rate of 55.2 per 1,000 catheter-days, preventing even 11.5% equates to approximately six infections avoided per 1,000 catheter-days. The difference between the two studies highlights the impact of human behavior and protocol adherence. Spigot Guard provides passive, continuous protection that does not rely on perfect compliance.

### Understanding Disconnection Rate in Catheter Systems

Disconnection rate refers to how often the closed drainage system is broken, meaning the sterile, sealed connection between the catheter and collection bag is opened or disrupted. Disconnections most commonly occur at junction points such as the catheter-to-drainage tube connection, sampling ports, and the drainage tube-to-collection bag interface. The drainage bag spigot is a critical access point where disconnections occur during emptying, sampling, or accidental opening. When the closed system is broken, bacteria can enter and migrate intraluminally, similar to breaking the seal on a sterile package.

### Disconnection Rate and Infection Pathways

The Mayo study reported a 10% disconnection rate and a 34% intraluminal infection rate, while the French ICU study reported a 3% disconnection rate and an 11.5% intraluminal infection rate. This threefold difference demonstrates a strong correlation between disconnection frequency and intraluminal infection risk. Even trained healthcare workers make errors, and each disconnection event represents a contamination opportunity.

## Common Reasons for Disconnections

Disconnections occur during necessary medical procedures such as urine sampling, drainage bag changes, and catheter irrigation. They also result from accidental tugging, improper handling during patient movement, equipment wear, and emergency situations requiring rapid intervention.

## How Spigot Guard Addresses This Risk

While Spigot Guard does not prevent disconnections at catheter junction points, it protects the drainage spigot, a high-risk site that is opened multiple times daily and exposed to direct hand contact, splashing, and biofilm formation. Even in high-compliance environments, the spigot remains a vulnerable point. Spigot Guard provides a final, passive layer of protection where behavioral compliance alone is insufficient.

