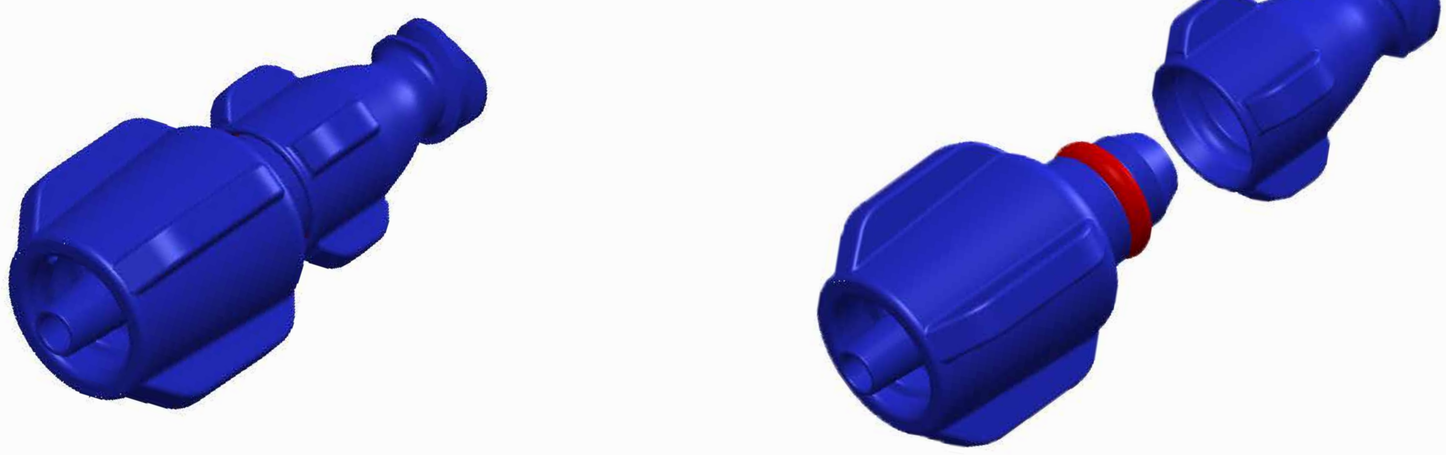
Safety Locks™



Catheter dislodgement is a well-known occurrence in patients with various types of drainage catheters. Every IR department has its own anecdotal experiences and the costs and frustrations related to the management of dislodged catheters. There is limited literature evaluating this, but some published studies describe dislodgement rates of 9-19%.

Catheter migration – catheter moves but tip is still in satisfactory position to allow functional usage. Should be revised/replaced.

Primary catheter securement – engineered catheter anchoring techniques at or near the catheter hub at the skin puncture site. Anchors the catheter.

Secondary catheter securement – reduces accidental pull forces transmitted by connecting tubing.

Catheter dwell time – time that catheter remains in situ and functional.

Catheter dislodgement – catheter moves and is no longer functional. Must be revised/replaced.

Catheter insertion and thus catheter dislodgement can occur in many situations.

- Percutaneous biliary drainage catheters
- Percutaneous gallbladder drainage catheters
- Percutaneous renal collecting system catheters
- Percutaneous abscess drainage catheters
- Percutaneous gastric and enteric feeding catheters
- Percutaneous venous access catheters such as PICCs
- Intraluminal feeding catheters such as nasogastric tubes
- Intraluminal bladder draining catheters such as Foley catheters

There are definite economic and health care costs related to catheter dislodgments.

- Primary replacement catheter cost
- Secondary equipment costs related to catheter reinsertion (eg. Wires, navigating catheters, anchoring devices)
- Procedural room time
- Human resource costs (nurses, IR techs, physicians)
- Injury to patient from catheter dislodgement trauma
- Increased morbidity to patient from new punctures that may be required

Conventional strategies to improve catheter dwell time have focused on the internal catheter design (eg. Pigtail tip, balloon tip, Malecot tip, distal catheter length, etc.) or the primary catheter anchor site (eg. suture technique, sutureless engineered products with or without adhesive components).

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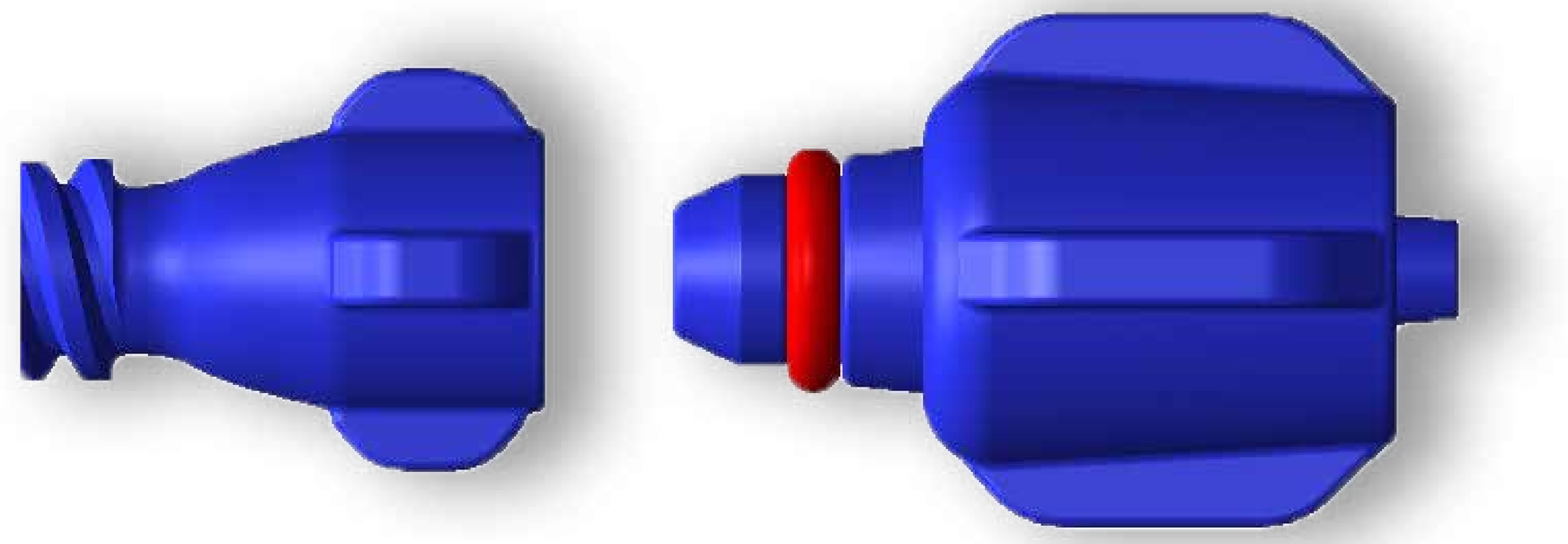
There have been some engineered devices focusing on secondary catheter securement (eg. Securacath) and practical “trouble shooting” solutions such as the use of stoma appliances and colostomy bags (thus precluding the use of connecting tubing).

Empirically, catheter dislodgement seems related to accidental forces applied on the connecting tubing. Typically, these are patient weight forces that occur when patients roll or move around in bed or when upright. Dislodgement of the primary drainage catheter occurs through transmitted pull forces. These pull forces can be significant depending on patient weight and type of movement. Empirically, no catheter design or primary catheter securement technique can accommodate the range of pull forces that may occur.



The -M- Safety Lock attaches to the Luer-lock connection between the primary catheter and connecting tubing. Functionally, the Luer-lock is unbreakable and therefore the primary catheter and connecting tubing act as one piece of equipment. Pull forces on the connecting tubing will be transmitted down the length of the tubing to the primary catheter without much impediment except beyond the strength of the primary catheter securement device. However, with the M-lock in place, the connection between the primary drainage catheter and the connecting tubing will break apart beyond a threshold pull force.

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