

# Risks of Reusing Catheters



180 Medical, Inc. strongly recommends that patients do not attempt to wash and reuse catheters, but instead use sterile catheters in order to preserve and enhance patient health and safety. Sterile catheters are Single Use Devices (SUDs). They are not approved by FDA to be washed and re-used. They were not designed to facilitate cleaning and sterilization. As a result, SUDs often have unique features such as acute angles, crevices, and joints and rough, porous or occluded surfaces that make access difficult, create barriers to cleaning and allow for the collection of blood, tissue and other organic matter. Household washing and re-using will almost always be incapable of penetrating this biological tissue residue, leaving potentially pathogenic bacteria, viruses and other microorganisms on the catheters which may infect or re-infect a patient on reuse.

Indeed, independent laboratories have conducted tests on *professionally* reprocessed low or moderate risk SUDs that break sterile or mucosal barriers (such as catheters) that were on hospital shelves ready to be used. In some instances, over 90% of the products tested positive for the presence of residual tissue, and more than 60% of the reprocessed products fell far below sterility standards established by the FDA. This was testing done on *professionally* washed and re-cleaned catheters. Can you imagine what a home-cleaned catheter must contain when it is washed and re-used? Moreover, methods traditionally used to destroy human and animal pathogens do not appear to destroy prions, the causative agent for spongiform encephalopathies such as Creutzfeldt-Jakob (Mad Cow) disease, raising particular concern regarding the reprocessing of devices used for invasive procedures. Even if sterility can be ensured, organic residue may still remain on reprocessed devices due to inadequate cleaning. Such sterile pyrogens, blood, tissue and other organic residue can trigger potentially fatal immune reactions.

Additionally, the reprocessing of devices intended for only one use can diminish the device's effectiveness by threatening the functional integrity of the used SUD. A SUD is designed for optimal single-use performance rather than ease of cleaning, and its structural integrity may be seriously compromised or destroyed by household rewashing and attempt at sterilization. For example, reprocessing can decrease rigidity and increase the incidence of catheter rupture, weaken structural integrity of PVC tubing and increase the risk of urethral trauma and infection. The diminished efficacy of reprocessed SUDs represents a significant risk to patient care.

See Dana Hawkins, *News You Can Use: Risky Recycling*, U.S. NEWS & WORLD REPORT (Sep. 20, 1999). A number of articles highlighting the risks associated with reprocessed SUDs appeared in several magazines and newspapers, including: Neil Weinberg, *Blood Money: Junkies reuse discarded medical equipment—and it turns out maybe you do, too, courtesy of cost-cutting hospitals*, FORBES (March 22, 1999); Dana Hakins, *Risky Recycling: That "disposable" catheter may have been used before*, U.S. NEWS & WORLD REPORT (Sep. 20, 1999); Gina Kolata, *'Single Use' Medical Devices are Often Used Several Times*, NEW YORK TIMES (Nov. 10, 1999).