

From the TMG Solutions Archives:

Actuating Lever Failure

Keywords - Failure, Environmental Stress Cracking

What Went Wrong?

The actuating levers on a high number of medical components cracked after a relatively short time in service, resulting in failure of the devices. The levers were injection molded from a poly(acrylonitrile:butadiene:styrene) (ABS) resin. The failures were isolated to a few installation locations.

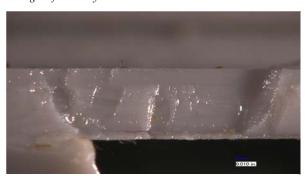
View of the fracture surface of a typical failed actuating lever. Multiple individual cracks are evident. The fracture surface shows

no signs of ductility.

Evaluation

Visual and microscopic examinations of the failed levers revealed features associated with brittle fracture, without signs of macro or micro ductility. The observed irregular, but continuous, fracture pattern indicated the initiation of multiple cracks that subsequently coalesced as they propagated through the wall of the lever. The fracture surfaces presented relatively smooth, sharp features, with signs of slow crack initiation and growth throughout the cracking. The observed features were characteristic of failure through environmental stress cracking (ESC), a failure mechanism whereby a plastic material cracks due to the contact with an incompatible chemical agent while under tensile stress.

Analysis of the fracture surface revealed the presence of a silicone-based chemical. Silicones are known to act as ESC agents in conjunction with ABS resins. The source of the silicone was thought to be a minor ingredient in one of the sanitizing agents used on the medical device. Environmental stress crack testing of the ABS resin with the sanitizing agent demonstrated incompatibility, with cracking in a short time period. even under conditions of moderate stress.



An area of crack initiation is shown. The features are characteristic of brittle fracture via a slow crack growth mechanism.

Sample 1 Fracture Surface Wipe

Sample 2 Fracture Surface Wipe

0.010 Sample 3 Fracture Surface Wipe

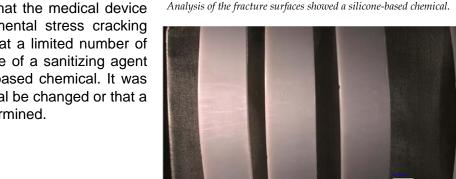
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Conclusion

It was the conclusion of the evaluation that the medical device actuating levers failed through environmental stress cracking (ESC). Failures occurred within devices at a limited number of installations because of the unique usage of a sanitizing agent that contained an incompatible silicone-based chemical. It was recommended that either the lever material be changed or that a list of compatible cleaning agents be determined.



Silicone Oil

ESC testing showed cracking in the lever material when in contact with the sanitizing agent while under stress.

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