

FDA Notice: Do NOT Report, Transfer, Donate or Sell STERIS System 1 Processor

We were recently informed by the Food and Drug Administration (FDA) regarding an item, the STERIS System 1 Processor (SS1), which the FDA explained should not be made available for transfer, donation or sale. The item, a STERIS System 1 Processor (SS1) is a tabletop liquid chemical system promoted to provide sterile processing of instruments, such as endoscopes, bronchoscopes, and other medical devices between patient uses. The SS1 uses a peracetic acid solution (STERIS 20 Sterilant) to destroy potentially dangerous microorganisms that could cause infections if left on medical devices. The SS1 is used in healthcare hospitals, outpatient surgical centers, and some physicians' offices. The STERIS System 1 Processor (SS1) is the exact same item as the STERIS Sterilizer and neither should be transferred, donated or sold under any circumstances.

The FDA took legal action against the STERIS company for this particular item and model because the FDA had not determined whether the item was safe or effective for its labeled claims. As part of this action, the Steris Company was responsible for contacting the agencies to whom the item was transferred, donated or sold, to advise them that this item was no longer to be used, and that they (the Agency) would have to transition to a different model. It is unclear if the agencies were aware that their procedures to dispose of this item meant that it was not to be reported for sale or reutilization.

This first came to GSA's attention when GSA Sales acquired this equipment because a VA facility was disposing of it through what they probably assumed were the proper channels. However, after speaking with the FDA, it is clear that this item SHOULD NOT BE TRANSFERRED, DONATED OR SOLD under any circumstances; not for parts only, or not in a mutilated state (like ATV's).

This is your formal notice that the STERIS System 1 Processor (SS1) or STERIS Sterilizer and STERIS 20 Sterilant solution ARE NOT TO BE TRANSFERRED, DONATED OR SOLD.

Please advise any customer Agencies (primarily medical entities) that maybe unaware that this mandate exists. If you or your customer Agencies should require additional information, please visit the FDA website at: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm for more information.