

CRIMINAL INFORMATION (Introduction of Misbranded Surgical Gowns in Interstate Commerce With Intent to Defraud and Mislead) 21 U.S.C. §§ 331(a), 333(a)(2)

The United States of America charges:

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1. From on or about November 1, 2014 through on or about January 15, 2015, in the

Northern District of Texas and elsewhere, the Defendant,

AVANOS MEDICAL, INC.,

with the intent to defraud and mislead, introduced and caused the introduction into interstate commerce medical devices, namely MicroCool surgical gowns, that were misbranded within the meaning of Title 21, United States Code, Section 352(a), in that the labeling of the gowns as

AAMI Level 4 under the 2012 ANSI/AAMI PB70 standard was false and misleading.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

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