

# 3M™ Sterilization Assurance Standards Practice

1 2 3 4

## Appropriate Placement of 3M™ Comply™ SteriGage™ Chemical Integrators

Why do AORN and AAMI recommend the use Chemical Indicators(CIs)? The use of CIs is part of an effective quality assurance program and assists in the detection of potential sterilization process failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer.<sup>1</sup>

The Association for the Advancement of Medical Instrumentation states, “An internal chemical CI should be used within each package, tray or rigid sterilization container system to be sterilized. The CI should be placed in that area of the package, tray or containment device (rigid container system, instrument case, cassette, or organizing tray) considered to be least accessible to steam penetration; for a containment device, the manufacturer’s instructions for placement of the CI should be consulted.”<sup>1</sup>

According to the Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Setting, “a chemical indicator/integrator should be placed inside each package and an external chemical indicator affixed outside each package to be processed.”<sup>2</sup> AORN says that for flash sterilization “Class 5 chemical integrating indicators should be used within each sterilizer container or tray.”<sup>2</sup>

### Peel Pouches

Place CI in geometric center.<sup>3</sup>



### Container supplied by the Manufacturer (multi-level, perforated tray, needs to be wrapped)

Place CIs in center on each level.<sup>3</sup>



### Flash Sterilization of Unwrapped, Perforated Instrument Trays

Place CI in the geometric center of unwrapped, perforated, instrument trays.<sup>3</sup>



### Wrapped Towel Pack or Gown, Towel and Drape Pack

Place CI in geometric center, not on top.<sup>3</sup>



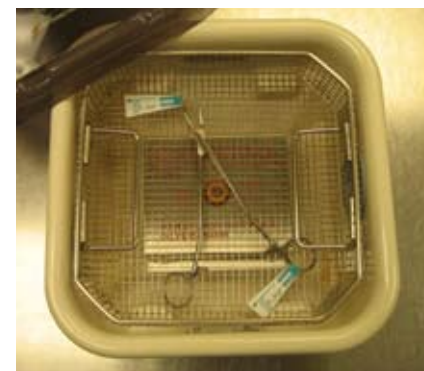
### Rigid Containers

Place two CIs inside rigid containers in opposite corners of each level.<sup>3</sup>



### Flash Sterilization of Rigid Containers

Place two CIs inside rigid containers in opposite corners.<sup>3</sup>



### Wrapped Instrument Tray

Place CI in geometric center, not on top.<sup>3</sup>



3M Comply SteriGage Chemical Integrators conform to ANSI/AAMI/ISO 11140-1:2005.

BSI, a leading global independent Product Testing Services Company, has confirmed through rigorous testing, that 3M Comply SteriGage Chemical Integrators meet the performance requirements of ISO 11140-1:2005.

<sup>1</sup> The Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2006 and A1:2008 (consolidated text).

<sup>2</sup> The Association of periOperative Registered Nurses. *Recommended Practices for Sterilization in Perioperative Setting*, 2009.

<sup>3</sup> The Association of periOperative Registered Nurses. *Recommended Practices for Selection and Use of Packaging Systems for Sterilization*, 2009.

