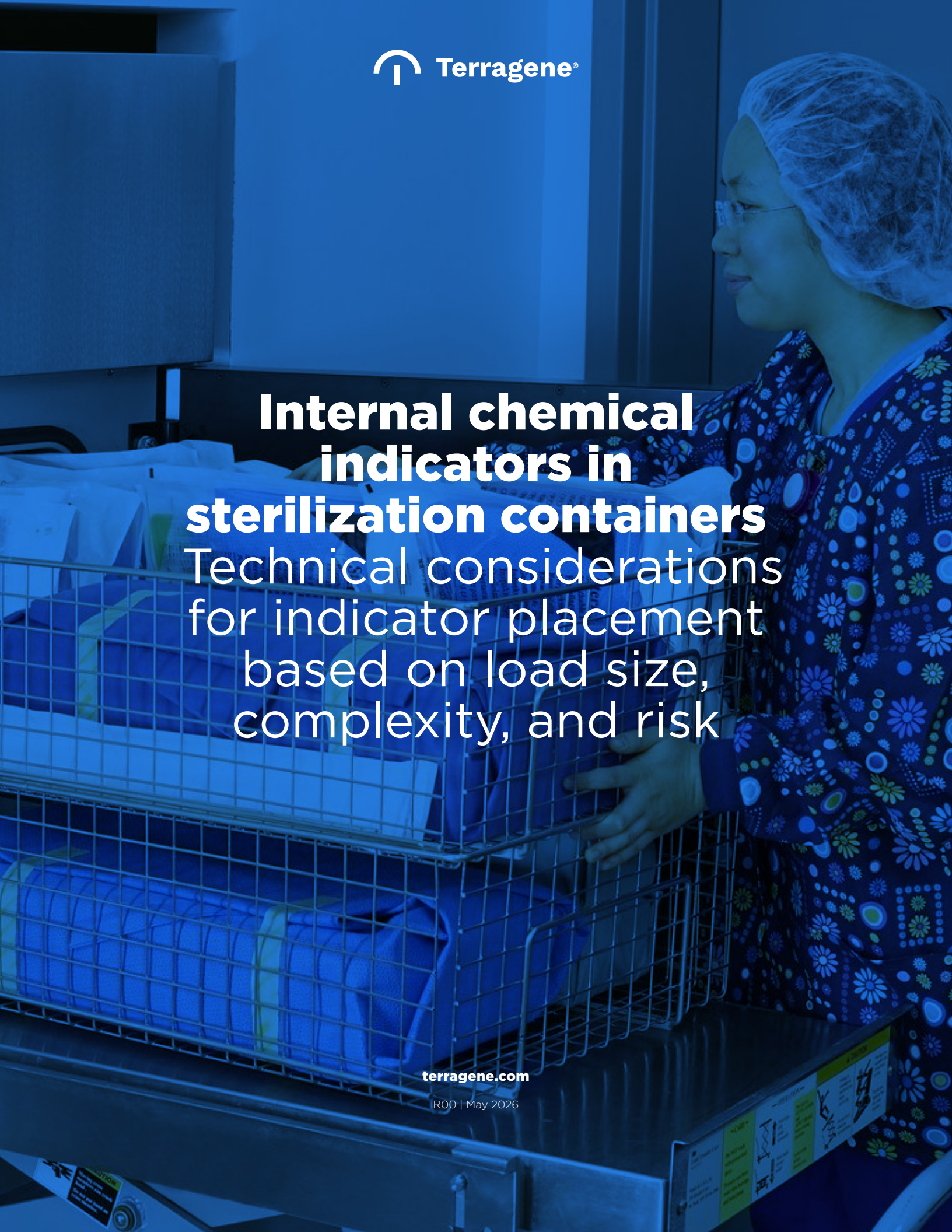
Terragene®



Internal chemical indicators in sterilization containers

Technical considerations for indicator placement based on load size, complexity, and risk

terragene.com

R00 | May 2026

EXECUTIVE SUMMARY
The use of internal chemical indicators (CIs) is a fundamental component of routine sterilization monitoring in healthcare sterile processing departments (SPDs/CSSDs). However, one recurring technical question remains insufficiently understood:
Should larger sterilization containers or more complex loads contain more than one internal chemical indicator?

Current international standards and best-practice guidelines do not establish a fixed formula based on container volume or liters of capacity. Instead, they consistently emphasize a risk-based approach focused on the most difficult areas for sterilant penetration.

This article reviews the technical rationale, applicable standards, and practical recommendations related to the number and placement of internal chemical indicators inside sterilization containers and complex instrument sets.

1. Introduction

Internal chemical indicators are designed to verify that sterilizing conditions have reached the location where the indicator is placed. Their purpose is not merely to confirm exposure to the sterilization cycle, but to challenge the process at the point considered most difficult for sterilant penetration.

As sterile barrier systems become larger, denser, heavier, or multi-layered, identifying a single representative "worst-case location" becomes increasingly difficult. This raises an important technical consideration:

Can a single internal CI adequately represent sterilant penetration throughout an entire large or complex container?

In many practical situations, the answer may be no.

2. What international standards Say

2.1 ANSI/AAMI ST79

The ANSI/AAMI ST79 guideline, widely recognized as a leading reference for steam sterilization in healthcare facilities, states that:
• "One or more" internal chemical indicators should be placed inside each package, tray, or rigid sterilization container.
• Indicators should be positioned in the area least accessible to sterilant penetration.
• The instructions for use (IFU) from both the container manufacturer and the CI manufacturer must be followed.

Importantly, ST79 intentionally avoids prescribing a fixed number of indicators based solely on container volume. Instead, it supports technical judgment and risk assessment.

This wording is significant because it explicitly allows the use of multiple internal indicators when justified by load complexity or design characteristics.

2.2 ISO 15882:2008

ISO 15882, which provides guidance for the selection, use, and interpretation of chemical indicators, reinforces the concept of point-of-placement monitoring.

The standard specifies that the internal CI should be located in the area of the package, tray, or container considered least accessible to the sterilizing agent. It also recognizes that this location may not correspond to the geometric center.

Notably, ISO 15882 explicitly acknowledges that:

Multiple indicators may be used in multi-level containers.

The standard also supports the use of indicators in different packages or locations to evaluate varying conditions inside the sterilizer chamber.

3. Why larger or more complex containers may require multiple indicators

The rationale is rooted in the physics of sterilant penetration.

Sterilizing agents such as steam do not distribute uniformly inside a loaded container. Instead, sterilant penetration is influenced by:
• air removal efficiency,
• load density,
• instrument mass,
• packaging configuration,
• lumens and narrow channels,
• thermal shielding,
• tray layering,
• and resistance pathways within the load.
In practice, a large rigid container behaves less like an empty chamber and more like a

microenvironment with localized conditions.

Different areas inside the same container may experience different sterilization challenges.

Examples include:
• corners distant from filters or valves,
• lower tray levels,
• dense instrument clusters,
• lumened devices,
• implant areas,
• and locations with restricted steam circulation.

For this reason, a single CI may not adequately represent the entire load in larger or more complex systems.

4. Practical approaches

Although standards do not provide a universal "X indicators per X liters" formula, several practical approaches are commonly adopted in healthcare facilities and recommended by manufacturers.

Load configuration	Common practice
Small peel pouch	1 internal CI
Simple wrapped tray	1 central CI
Medium or large rigid container	2 CIs in opposite corners
Multi-level set	1–2 CIs per level
Implant or highly complex set	Additional CI near the most critical challenge area

These practices are generally derived from:
• risk assessment,
• validation studies,
• manufacturer IFUs,
• and professional sterile processing experience.

5. Manufacturer Instructions for Use (IFUs)

Manufacturer instructions are a critical regulatory component.

Several rigid container manufacturers and CI manufacturers specify:
• the number of indicators,
• placement locations,
• monitoring points per level,
• and validated loading configurations.

Some manufacturers recommend placing indicators:
• in opposite corners,
• in each tray layer,
• or at multiple challenge locations inside rigid containers.

When these instructions are part of validated device IFUs, they should no longer be viewed merely as recommendations or "good practices," but as validated conditions of use.

6. Technical interpretation

From a technical standpoint, the number of internal indicators should not be determined solely by container size.

Instead, the following questions should guide decision-making:
• Does the container contain multiple levels?
• Are there several independent worst-case locations?
• Is the load dense or highly complex?
• Are implants or lumened devices present?
• Could different areas experience different sterilization conditions?
• Do the manufacturer IFUs specify multiple monitoring points?

If the answer to one or more of these questions is yes, the use of multiple internal indicators may be technically justified and preferable.

7. Conclusion

There is currently no universal standard or guideline establishing a strict formula such as:

"X number of indicators per X liters of container volume."

However, international standards consistently support a risk-based approach centered on the most difficult areas for sterilant penetration.

As load size and complexity increase, the likelihood of multiple critical monitoring locations also increases.

Ultimately, the number and placement of internal chemical indicators should be determined through:
1.Manufacturer IFUs
2. Load configuration analysis
3.Sterilization validation principles
4.Institutional risk assessment
5.Clinical and technical judgment
In modern sterile processing practice, internal chemical indicators are no longer viewed simply as process accessories. They are increasingly recognized as strategic monitoring tools for challenging sterilization conditions where sterilant penetration may vary within the same load.

References

• ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities
• ISO 15882:2008 Sterilization of health care products – Chemical indicators – Guidance for selection, use and interpretation
• Manufacturer IFUs for rigid sterilization containers and chemical indicators
• Published sterile processing best practices and professional SPD/CSSD guidance