

# **Advantages and limitations of class 5 and 6 indicators according to EN-ISO 11140-1 for steam sterilization processes**

## **AGENDA**

- 1. Definition of indicator classes**
- 2. Critical parameters of steam sterilization processes according EN-ISO 11140-1**
- 3. Advantages of class 5 and 6 indicators**
- 4. Role of Non Condensable Gases (NCG)**
- 5. Limitations of class 5 and 6 indicators**
- 6. Solutions to overcome those limitations**

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# Classification of chemical indicators for different sterilization processes according to the International standard EN-ISO 11140-1

<b>Class</b>	<b>Description</b>
<b>I</b>	<b>Process indicators</b>
<b>II</b>	<b>Indicators for specific use (Details are found in other Standards)</b>
<b>III</b>	<b>Single parameter indicators</b>
<b>IV</b>	<b>Multi-parameter indicators</b>
<b>V</b>	<b>Integrating indicators (emulating biological indicators)</b>
<b>VI</b>	<b>Emulating indicators</b>

# **Critical parameters of steam sterilization processes according EN-ISO 11140-1 (written in point 5.2)**

- 1. Time**
- 2. Temperature**
- 3. Water (as delivered by saturated steam)**

**Not mentioned is the critical parameter Non Condensable Gases (NCG).  
NCG may occur in steam by:**

- 6. Insufficient air removal from the sterilization chamber**
- 7. Leaks during the vacuum phase**
- 8. Being delivered in steam because of various reasons**
- 9. Coming from pneumatically actuated leaking door seals**

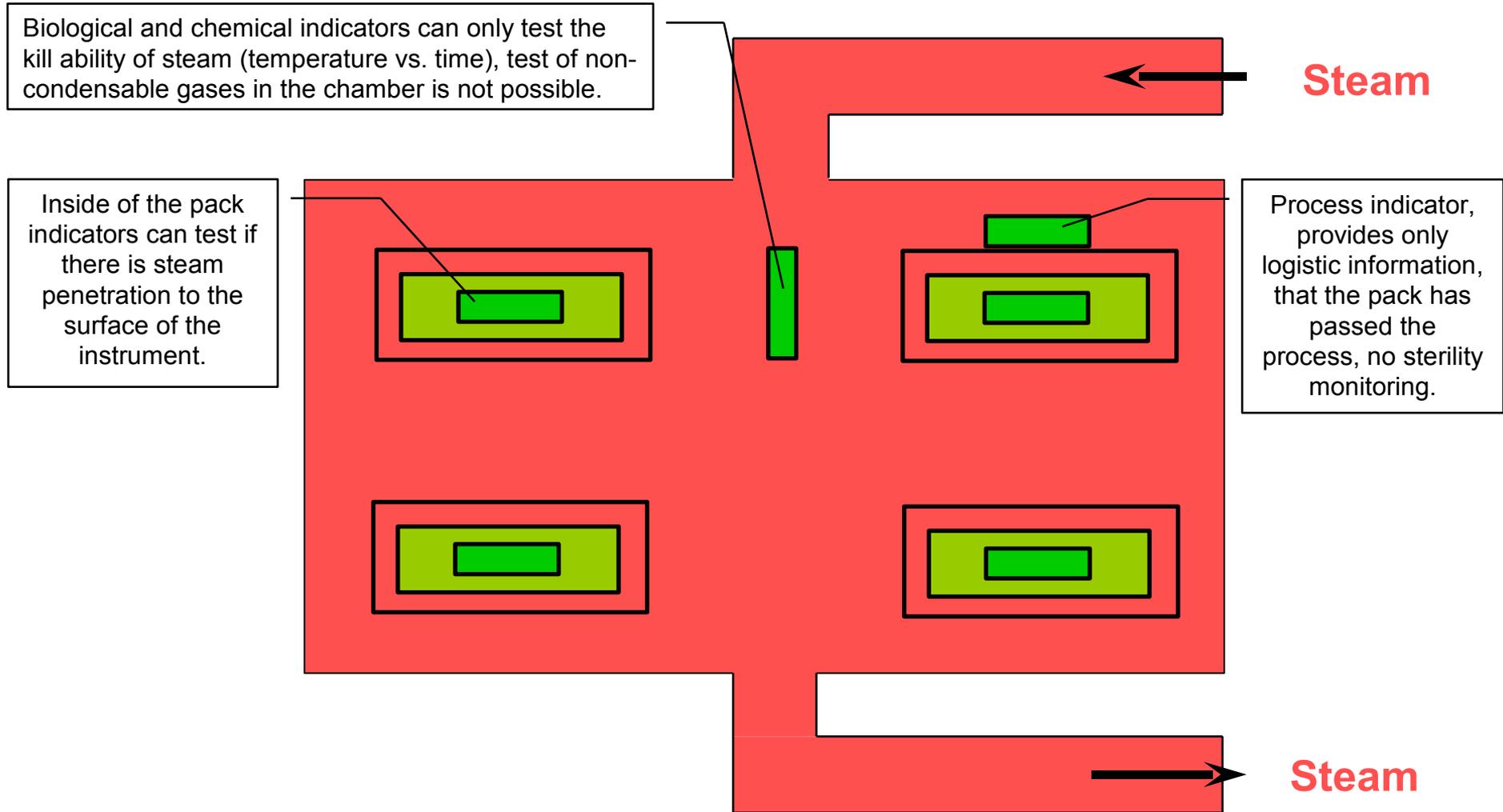
## **Advantages of class 5 and 6 indicators**

**Class and 5 and 6 indicators can monitor the necessary parameters time, temperature, water according to the required  $F_0$ -values at the place those indicators are located within a sterilization process.**

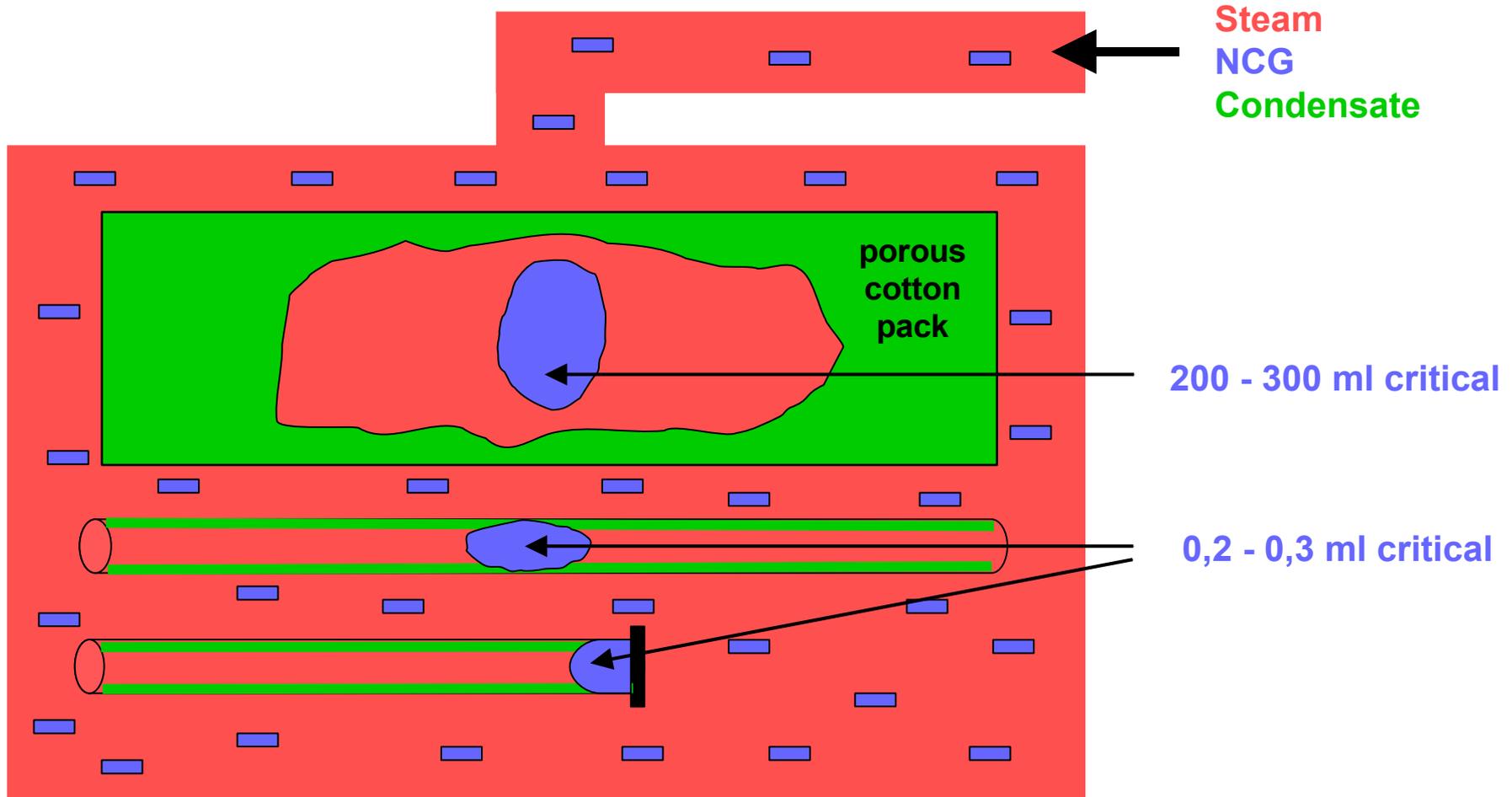
**They can replace biological indicators giving the same sterilization security with the advantage that there is no incubation time for chemical indicators necessary and the result of the process is immediately available at the end of the process under the condition the indicator is visible.**

**They must be placed at the most difficult penetration location within the sterilization chamber.**

# Effect of the different positions of chemical indicators inside steam sterilization processes



# Separations of non-condensable gases (NCG) in porous loads and hollow instruments



Ratio of the critical NCG amounts:  
porous : hollow  $\approx$  1.000 : 1

## **Limitations of class 5 and 6 indicators**

- 1. They can only monitor sterility at those places where they are located.**
- 2. They cannot secure the whole process.**
- 3. They cannot detect Non Condensable Gases in steam mixtures, only if the NCG are accumulated in packs.**
- 4. Since chemical indicator strips cannot be placed inside of minimal-invasive-surgical (MIS) instruments, they cannot secure any lumen instruments or tubes.**

## Test device for various applications

It is used to substitute instruments, packs with instruments and/or whole load configurations

<b>P</b>	rocess
<b>C</b>	hallenge + Indicator
<b>D</b>	evice

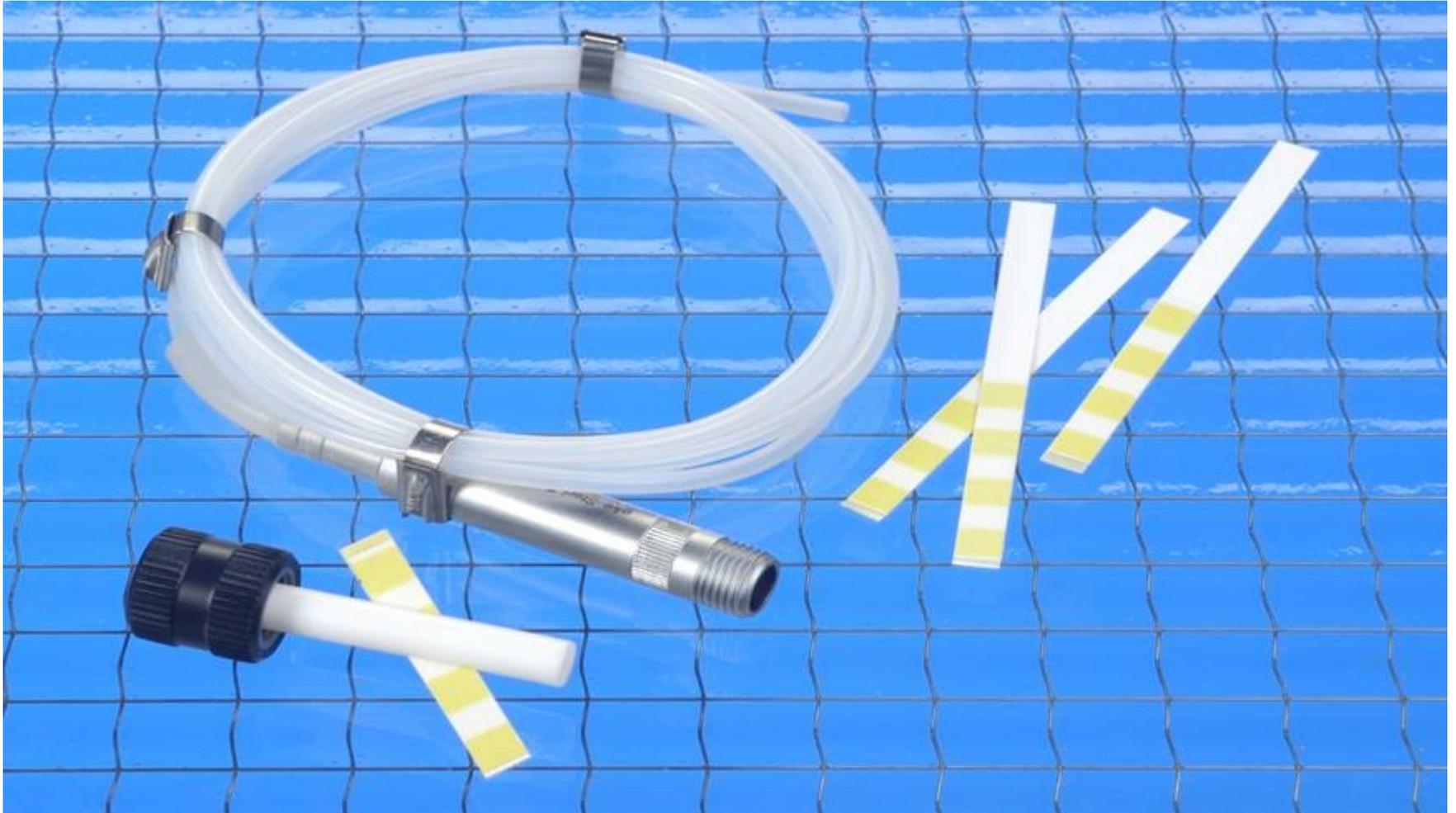
A PCD with an indicator inside is called an indicator system.

The PCD is monitoring the penetration characteristics.

The indicator is monitoring the presence of sterilization agent and the temperature time integral at the worst case location.

Those indicator systems are class 2 indicators according EN-ISO 11140-1

**Helix-PCD® according to EN 867-5 Hollow A  
for sterilizer type testing, validation and batch monitoring**



# Compact-PCD<sup>®</sup> - sectioned -



- Durable for multiple use
- Adjustable for various applications simulating solid, porous and hollow devices
- PCD can be used as MPS and BMS

# **Solutions to overcome the limitations of class 5 and 6 indicators using Process Challenge Devices (PCDs)**

## **1. Medical Device Simulators (MDS)**

**Simulation of the steam penetration characteristics of hollow instruments by using special PCDs called Medical Device Simulators (MDS). The MDS must be put alternatively or together in the same type of pack and can be taken out at the end of the process and checked.**

## **2. Batch Monitoring System (BMS)**

**Simulation of the worst case steam penetration conditions of the whole load including all packages at the worst case place within the chamber. The result of the BMS is available at the end of the process.**

