

## Biological Indicator Tests and Quarantining Instruments

A PCD (test pack) with a biological indicator (BI) must be run at the beginning of each day the sterilizer is used and for each cycle type. Manufacturer's instructions must be followed on *how* the test should be run for the PCD test packs (e.g., whether the test pack should be run on a full or empty load).

The timeframe for processing BI tests varies depending on the system purchased (from less than an hour to 24 hours)



### **Class 4 CIs**

If Class 4 chemical indicators (CIs) are used in each package/cassette/pouch, the instruments in the test load and each subsequent load in that sterilizer **MUST** be quarantined until a negative BI test result is confirmed.

### **Class 5 CIs**

If Class 5 chemical indicators (CIs) are used in each package/cassette/pouch, the instruments in the test load and each subsequent load in that sterilizer may be used without quarantining prior to the confirmation of a negative BI test.

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## Implantable Devices

Implantable devices and instruments used to place them must be sterilized using a BI (in each load) and cannot be used until a negative BI for that load is confirmed. This is regardless of whether a Class 4 CI or Class 5 CI is used in each package/cassette/pouch.

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# FAQs Regarding Sterilizer Monitoring

(March 1, 2023)

## What are chemical indicators?

Chemical indicators (CIs) indicate that one or more physical process variables for sterilization have been met (e.g., time, temperature, pressure).

The CIs used most commonly in dentistry are:

- **Class 1 CIs** respond to one or more critical process variables (typically on the outside of a package/cassette/pouch)
- **Class 4 CIs** respond to two or more critical process variables
- **Class 5 CIs** respond to all critical process variables.

**Each** instrument package/cassette/pouch **MUST** have a Class 1 CI on the outside and a Class 4 or Class 5 CI on the inside.

## What are biological indicators?

Biological indicators (BIs) use resistant spores in a vial which are incubated after being run through a sterilization cycle. A negative BI test confirms that these spores have been killed and, by extension, so have other potential pathogens in the load.

## What is a process challenge device?

A process challenge device (PCD) is also known as a “biological test pack”. It simulates an equal or greater challenge than the most difficult instrument/device set routinely processed for that sterilizer and/or cycle. It is placed in an area of the sterilizer known to be most challenging to achieve sterilization (as per manufacturer’s instructions).

There are commercially available PCDs, but they can be made in-office using decommissioned instruments and a BI in a package/cassette.

A PCD (test pack) with a BI must be run at the beginning of each day the sterilizer is used and for each cycle type. Manufacturer’s instructions must be followed on *how* the test should be run for the PCD test packs (e.g., whether the test pack should be run on a full or empty load).

## When can instruments in the test load and subsequent loads be used?

Instruments in the test load and each subsequent load must be quarantined (not used) until the result of the BI test comes back negative **UNLESS** a Class 5 indicator is used in each package/cassette/pouch.

Exception: All **implantable devices and instruments used to place them** must be sterilized using a BI (in each load) and cannot be used until a negative BI for that load is confirmed.

**Can I use Class 4 rather than Class 5 CIs inside each package/cassette/pouch?**

Yes, but the instruments MUST be quarantined (not used) until a negative BI result is confirmed for that sterilizer that day. In addition, at least one Class 5 CI MUST be used in each load.

Best practice is to use a Class 5 CI in each package/cassette/pouch.

**Are pouches with integrated internal Class 4 CIs equivalent to separately inserted Class 4 CIs?**

Yes.