

(See *Sterilization Monitoring Section of IPAC Standards* for full details)

A process challenge device (PCD) with a biological indicator (BI) test **MUST** be run through a full load for each sterilizer and each cycle type at the beginning of each day.

The timeframe for processing BI tests varies depending upon 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.

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.
