	Technical Information	730-129-EN		V03
	Advantage using PCDs to monitor steam sterilization processes	Created	19.09.2014	UK
		Changed	06.08.2021	KP
		Checked	06.08.2021	UK
		Released	06.08.2021	UK
		File no.: 0.3 + 1.1		

Traditionally biological indicators are used for sterilization monitoring. They cannot be placed inside a package, because they must be taken out before the package is opened and the instruments inside are used. The disadvantage using biological indicators outside of a pack is that they do not monitor the sterilization conditions inside of a pack or inside an instrument but testing the sterilizer chamber conditions only.

Inside a sterilizer chamber there are no homogenous conditions and outside of packs there is the best steam penetration distribution while inside of packs and inside of instruments there are more difficult requirements to get sufficient air removal and steam penetration. Accordingly a biological or chemical indicator outside of a pack can never determine sterility inside of packs and inside of hollow instruments.

To assure the sterilization inside of packs and inside of hollow devices normally biological indicator suspension must be inoculated inside of hollow instruments at the worst-case location. However this is only a one-time procedure which is called performance qualification (PQ) according to EN ISO 17665-1 which is part of validation of a sterilization process.

Since this direct inoculation procedure cannot be used for routine monitoring, special devices simulating the hollow instruments in packs have been designed, so-called “Process Challenge Devices (PCDs)”. If biological or chemical indicators are put inside, they simulate that a BI, SCBI or chemical indicator has the same steam penetration conditions as inside of an instrument in a pack and can therefore assure sterility, if the biological indicator inside of the PCD is inactivated or chemical indicator has changed its color to pass.

This procedure is the only possibility in routine monitoring to check the result of sterilization processes in comparison putting a lot of biological indicators outside of packs in the sterilizer.

For routine monitoring the same procedure is recommended in the validation and routine monitoring standards EN ISO 14937 and EN ISO 17665-1 (see TI730-175).