

Process Challenge Device (PCD)

Quality certification

Certificado de calidad

STEAM

LOT

CE

MD

BT222 SCBI

Geobacillus stearothermophilus ATCC® 7953

LOT

Heat shock population / Población _____ CFU / UFC

D-value / Valor D (121 °C) (*) _____ min.

Survival time / Tiempo de sobrevida _____ min.
Survival time = $(\log_{10} \text{ labeled population} - 2) \times \text{labeled D-value}$

Kill time / Tiempo de muerte _____ min.
Kill time = $(\log_{10} \text{ labeled population} + 4) \times \text{labeled D-value}$

D-value / Valor D (132 °C) (*) _____ sec./seg.

Survival time / Tiempo de sobrevida _____ min.
Survival time = $(\log_{10} \text{ labeled population} - 2) \times \text{labeled D-value}$

Kill time / Tiempo de muerte _____ min.
Kill time = $(\log_{10} \text{ labeled population} + 4) \times \text{labeled D-value}$

D-value / Valor D (135 °C) (*) _____ sec./seg.

Survival time / Tiempo de sobrevida _____ sec./seg.
Survival time = $(\log_{10} \text{ labeled population} - 2) \times \text{labeled D-value}$

Kill time / Tiempo de muerte _____ min.
Kill time = $(\log_{10} \text{ labeled population} + 4) \times \text{labeled D-value}$

Z-value / Valor Z _____ °C

Parameters determined at time of manufacture according to ISO 11138-1: 2017, ISO 11138-3: 2017 and IRAM 37102: 1999 (Parts 1 and 3) standards. The values shown are reproducible only under the same conditions under which they were determined.

Parámetros determinados al momento de la fabricación según normas ISO 11138-1: 2017, ISO 11138-3: 2017 e IRAM 37102: 1999 (Partes 1 y 3). Los valores presentados son reproducibles solo bajo las mismas condiciones en las cuales fueron determinados.

ISO and USP Compliant
Terragene® and *Bionova®* are registered trademarks of Terragene S.A.
ATCC® is a registered trademark of American Type Culture Collection.

* Determined by the fraction negative method

IT26-C Chemical Integrator

LOT

Stated Values (SV)

Temperature	Time
121 °C	_____ min.
128 °C	_____ min.
135 °C	_____ min.

SV – stated value: Value of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.

According to ISO 11140-1:2014 standard

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Technical Director

Uso exclusivo para profesionales e instituciones sanitarias
Producto autorizado por ANMAT PM 1614-4

Explanation of Symbols

	Product designed for use with Steam sterilization cycles.		Medical Device.
	CE mark.		Batch number.
	Authorized representative in the European Community.		Manufacture Date.
			Expiration Date.
			Manufacturer.

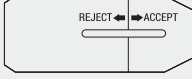
ATTENTION: If your chemical indicator has this logo printed on it, it means that your product is compatible with exclusive **Trazanto** Automatic Quality Control and Traceability System for cleaning, disinfection and sterilization processes.
This System interprets the indicator's results in an accurate and automatic manner, and stores all the process data through **Bionova® Software**. Use **Trazanto** scanner to interpret the results (see instructions for use in the manual of the device).
ATTENTION: Do not write on the indicator before scanning.

Intended Use Table

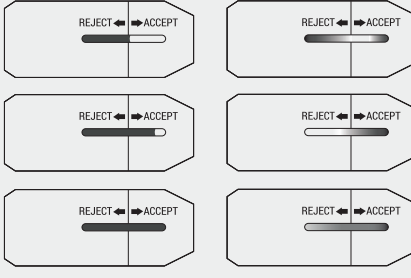
Model	Autoclave/Steam Cycles		
	Gravity Displacement		
PCD222-C	121 °C	132 °C	135 °C
	30 minutes	15 minutes 25 minutes	10 minutes
	Dynamic Air Removal (Vacuum Assist)		
	121 °C	132 °C	135 °C
	NA	4 minutes	3 minutes
	Fluorescence Read Time	pH Color Change	
1 hour	48 hours		

Result reference guide

Unprocessed



Accept



Reject



EN Process Challenge Device

For a rapid and easy monitoring of Steam sterilization processes

Indications for Use

United States

Terragene® Bionova® PCD222-C provides a defined challenge resistance against the claim cycle shown below and also demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring and sterilizer qualification testing steam sterilization processes. See Intended Use Table for reference.

Outside the United States

Bionova® PCD222-C Steam Process Challenge Device has been designed for quick and easy monitoring of dynamic air removal and gravity air displacement Steam sterilization processes at 132/135 °C ≥ 4 minutes and at 121 °C ≥ 30 minutes.

Device Description

Bionova® PCD222-C Process Challenge Device (PCD) Test Pack has been designed to simulate a load to be sterilized and to pose a challenge to the sterilization process. It is used to evaluate the effective performance of the process by detecting inadequate air removal and steam penetration. It also allows release of routine loads, especially implants. Furthermore, it allows to perform the routine monitoring and periodic validation of the sterilizers (after repair, installation, relocation).

Bionova® PCD222-C consists of a disposable pre-assembled package as outlined in ANSI/AAMI ST79 which contains a BT222 Self-Contained Biological Indicator (SCBI), a PCDBI-C-RC Record Card and an IT26-C moving front chemical integrator (Type 5 according to ISO 11140-1:2014 standard) that gives instant visible indication that sterilizing conditions have been reached.

Each pack consists of a stack of porous cards holding a self-contained biological indicator tube that contains a population of *Geobacillus stearothermophilus* ATCC® 7953 spores soaked on a carrier as well as growth indicator medium contained in a glass ampoule. Each SCBI has a process indicator (Type 1 according to ISO 11140-1:2014 standard) on label that changes from pink to brown when exposed to steam. The moving front chemical integrator shows ACCEPT result when sterilization conditions were reached while process indicator (Type 1 according to ISO 11140-1:2014 standard) on PCD box changes from light blue to grey when exposed to steam.

Precautions

WARNING: Do not use PCD for monitoring Ethylene Oxide, Dry Heat, Formaldehyde or any sterilization process other than Steam. Do not reuse biological indicators.

WARNING: Place one or more PCDs in sterilizing hard-to-reach areas to ensure all areas of the chamber are sterilized. Evaluate all load configurations to ensure ALL hard-to-reach areas have been identified, and place a PCD in each of those locations.

WARNING: Do not reuse the sterilizer until the biological indicator test result is negative.

Instructions for Use

- Place the pack inside a normally loaded steam autoclave, in those areas which are considered most inaccessible for the sterilizing agent (e.g., the center of the load and areas near the door).
- Run the sterilization cycle.
- After the sterilization process has finished, open the sterilizer door, wait for 5 minutes and remove the test pack. **NOTE:** The color of the box may vary from the original after undergoing the sterilization cycle. This does not represent a problem regarding the operation or quality of the product.
- Check that the process indicator printed on box has changed color from light blue to grey. Open the test pack, wait 5 minutes and remove the SCBI. Allow it to cool down to room temperature. **PRECAUTION:** Wear safety glasses and gloves when removing the biological indicator from the sterilized test pack. **WARNING:** Do not crush or handle the biological indicator excessively, since this might cause the glass ampoule to burst.
- Check IR26-C moving front chemical integrator for correct exposure. If the dark bar has reached the ACCEPT zone, this confirms that the inside of the pack has been exposed to correct sterilization conditions.
- Check the process indicator printed on SCBI's label. A color change to brown confirms that the biological indicator has been exposed to steam. **IMPORTANT:** This color change does not indicate that the process was sufficient to achieve sterility.
- Identify the Bionova® BT222 SCBI by writing the sterilizer number (in

case of having more than one), load number, and processing date on the label. Fill out the required information on the Record Card.

8. Press the cap to seal the tube. Crush the glass ampoule contained in the SCBI with an individual ampoule crusher or with the ampoule crusher placed within the incubator's incubation area. Then shake the tube down vigorously, until the medium reaches the base of the tube and soaks the spore carrier entirely. Incomplete wetting of the spore carrier may lead to an incorrect fluorescence readout. **IMPORTANT:** Use a non-sterilized biological indicator as a positive control in order to ensure that correct incubation conditions were met; capability of culture medium to promote rapid growth; no alteration of spore's viability due to improper storage temperature, humidity or proximity to chemicals and also correct functioning of Terragene® Bionova® Auto-reader Incubator. Both, the positive control indicator and the processed indicator, should belong to the same batch.

9. Incubate the processed biological indicator and the indicator used as positive control in Terragene® Bionova® Auto-reader Incubators for 1 hour at $(60 \pm 2) ^\circ\text{C}$ to get the final fluorescence result. A 48-hour readout is optional to culture medium color change after the 48-hour incubation) means failure of sterilization process. If a negative fluorescence result is obtained (or culture medium remains the original color after 48-hour incubation), it means that sterilization process was successful.

10. Record the SCBI and integrator results and adhere the self-adhesive Record Card or, alternatively, only the area containing the integrator indicator. **WARNING:** Do not use the sterilizer until the biological indicator test results are negative.

11. Discard the pack and the indicators immediately.

NOTE: If any serious incident occurs in relation to the device, it should be reported to Terragene S.A. and the competent authority of the State in which the user is established.

Monitoring frequency

Follow the policies and procedures with the monitoring frequency specified by the professional associations and/or standards corresponding to your country. As recommended practice, and to provide optimal patient safety, Terragene® recommends that each sterilization load be monitored with the appropriate biological indicator.

Storage

Store in a dark place, at temperatures between 10-30 °C, 30-80 % relative humidity. Do not freeze. Do not store near sterilizing agents or other chemical products.

Self Life

PCD222-C has an expiration date of 2 years from the date of manufacture, given by SCBI that carries, when stored at recommended conditions. Do not use after expiration date. Chemical Integrators and Process Indicators have an expiration date of 2 years when used in/on PCD.

Endpoint Stability Reaction: chemical indicator endpoint shall remain unchanged for a period of not less than 6 months when stored at previously indicated conditions.

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicators can be autoclaved in a gravity air displacement steam sterilizer at 121 °C for 30 minutes, 132 °C for 15 minutes or 134 °C for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C for 4 minutes or 135 °C for 3 minutes.

ES Dispositivo de Desafío de Proceso

Para el monitoreo rápido y fácil de procesos de esterilización por Vapor

Indicaciones de Uso

Estados Unidos

Terragene® Bionova® PCD222-C proporciona un desafío definido de resistencia al ciclo declarado a continuación y también una equivalencia de resistencia demostrada al paquete de 16 toallas especificado por AAMI/ANSI. El dispositivo permite llevar a cabo el monitoreo de rutina y la calificación del esterilizador ensayando procesos de esterilización por vapor. Ver Tabla de uso previsto.

Fuera de los Estados Unidos

El dispositivo de desafío del proceso Bionova® PCD222-C ha sido diseñado para un monitoreo rápido y sencillo de procesos de esterilización por vapor con remoción dinámica de aire o con desplazamiento de aire por gravedad a 132/135 °C ≥ 4 minutos y a 121 °C ≥ 30 minutos.

Descripción del producto

El dispositivo de desafío del proceso (PCD, Process Challenge Device) Bionova® PCD222-C ha sido diseñado para simular una carga a esterilizar y constituir un desafío al proceso de esterilización. Se utiliza para evaluar el efectivo desempeño del proceso mediante la detección de la inadecuada remoción de aire y la penetración de vapor. También permite la liberación de cargas de rutina, especialmente implantes. Además, permite realizar el monitoreo de rutina y la validación periódica del esterilizador (después de la reparación, instalación, reubicación).

Bionova® PCD222-C consiste en un paquete pre-ensamblado desechable como se describe en ANSI/AAMI ST79, el cual contiene un indicador biológico auto-contenido (SCBI, Self-Contained Biological Indicator) BT222, una Tarjeta de Registro PCDBI-C-RC y un integrador químico de frente móvil IT26-C (Tipo 5, según la norma ISO 11140-1:2014) que proporciona una indicación visible instantánea de que se han alcanzado las condiciones de esterilización.

Cada paquete consiste en un sistema de tarjetas porosas que contienen un tubo de indicador biológico auto-contenido con una población de esporas de *Geobacillus stearothermophilus* ATCC® 7953 inoculadas en un portador, así como un medio indicador de crecimiento contenido en una ampolla de vidrio. Cada SCBI tiene un indicador de proceso (Tipo 1, según la norma ISO 11140-1:2014) en la etiqueta que virá de rosa a marrón cuando se expone al vapor. El integrador químico de frente móvil muestra un resultado ACCEPT (aceptado) cuando se alcanzan las condiciones de esterilización, mientras que el indicador de proceso (Tipo 1, según la norma ISO 11140-1:2014) en la caja PCD virá de celeste a gris cuando se expone al vapor.

Precauciones

ADVERTENCIA: No usar el PCD para monitorear procesos con óxido de etileno, calor seco, formaldehído o cualquier proceso de esterilización distinto al Vapor. No reutilizar los indicadores biológicos.

ADVERTENCIA: Colocar uno o más PCDs en áreas difíciles de alcanzar por el agente esterilizante para asegurarse de que todas las áreas de la cámara estén esterilizadas. Evaluar todas las configuraciones de carga para asegurarse de que TODAS las áreas difíciles de alcanzar hayan sido identificadas y colocar un PCD en cada una de esas ubicaciones.

ADVERTENCIA: No reutilizar el esterilizador hasta que el resultado de la prueba del indicador biológico sea negativo.

Instrucciones de uso

- Colocar el paquete dentro de un autoclave de vapor junto con la carga habitual a esterilizar en aquellas áreas consideradas más inaccesibles para el agente esterilizante (por ejemplo, el centro de la carga y las áreas cercanas a la puerta).
- Ejecutar el ciclo de esterilización.
- Después de finalizado el proceso de esterilización, abrir la puerta del esterilizador, esperar 5 minutos y retirar el paquete de prueba. **NOTA:** El color de la caja puede variar del original luego de someterse al ciclo de esterilización. Esto no representa ningún problema en cuanto al funcionamiento o la calidad del producto.
- Verificar que el indicador de proceso impreso en la caja haya cambiado de color celeste a gris. Abrir el paquete de prueba, esperar 5 minutos y retirar el SCBI. Permitir que se enfríe a temperatura ambiente. **PRECAUCIÓN:** Usar gafas y guantes de seguridad cuando se retire el indicador biológico del paquete de prueba esterilizado. **ADVERTENCIA:** No aplastar ni manipular el indicador biológico en exceso, ya que esto

