



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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TEST HELIX DI BOWIE DICK **BOWIE DICK HELIX TEST** **TEST HÉLIX DE BOWIE DICK** **PRUEBA HELIX BOWIE DICK**

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

This direction for use is applicable for the following Sterintech products (Stat-
ed Value: 134°C-3,5min/121°C-15min):

Bowie Dick Helix Test with 100 indicators

Note: upon receipt of goods please check whether the package was undam-
aged and ensure you about the expiry date of the chemical indicators.

The Helix PCD incorporated in these products are EN 867-5 compliant :

Hollow Load Process Challenging Device EN 857/5 Steam

Introduction

The BDHT and its indicator strips are used for Bowie Dick Tests in pre-vacuum
Hospital steam sterilizers and Class B Bench Top Steam Sterilizers. The Bowie
Dick Test delivers the proof of proper functioning of the steam sterilizer.

During steam sterilization a number of problems can occur.
These can be a.o. presence of air in steam feed-in, Inert gases in generated
steam or leakage of door seals but also low temperature or short holding
times.

The print out parameters or chart of the recorded parameters by the steam
sterilizers control is not sufficient to guarantee that sterilization conditions
have been met in the complete chamber.

Some of the above-mentioned disturbances cannot be detected by pressure
and temperature sensors.

The BDHT is able to detect

- Sterilization temperature too low
- Sterilization holding time too short
- Insufficient vacuum in depth and in number of vacuum pulses.
- Insufficient air removal from hollow A devices
- Insufficient steam penetration in hollow A devices
- Leakage of piping / valves / door seals
- Detection of presence of small volume inert gases
- Detection of excessive amounts of condensate

The indicator fields of the indicator strip are covered by a lacquer and therefor
no ink or any substance from the ink can migrate on your instrumentation. The
indicator ink is not containing any dangerous or toxic components and can be
discarded as normal waste.

How to use the BDHT

- I. Take one of the indicator strips out of the plastic bag and close the bag in
order that the indicators strips are protected against humidity.
Bend the indicator strip in the middle in order that the indicator fields
are pointing inwards.
- II. Take the Helix and unscrew the cap.
- III. Place the indicator strip into the cap in such a way that bended end is
going into the cap as first.
- IV. Close the Helix by screwing the cap incl. the indicator strip on the holder.
- V. Place the Helix into the cotton bag and place it in an instrument tray near
to the bottom of the steam sterilizer.
Never place the Helix on the bottom of the sterilizer.
- VI. Run the Bowie Dick sterilization cycle

VII. After completion of the sterilization cycle and cooling off during a few
minutes take the Helix and remove it from the cotton bag. Condensate
may drip out of the Helix.

VIII. Unscrew the cap and take the indicator strip form the cap (eventually
use a plier)

IX. Judge the color change of the indicator. When all 4 indicator fields are
completely pink the sterilization cycle has been successfully. You may
use the color reference label for the end color judgement.

X. Dependent on the color change the staff may release the sterilizer to be
used for the day.

XI. Remove the indicator strip double adhesive strip from the back and glue
it into the daily documentation sheet.

XII. Add the sterilizer number, cycle number, date and release data on the
sheet.

XIII. In case the Helix or its tube has been wetted by condensate, blow some
compressed air through the Helix and let it dry in open condition.

Warnings

The indicator strips and Helix system are designed according to ISO 11140
and may not be used in combination with other indicator strips or other Helix
systems as this may lead to malfunction and misinterpretations of the test
results.

The plastic Helix device may not be dismantled or show any external damage
before use. These defective, dismantled, damaged Helix devices should be
replaced by a new Helix device in order to have right interpretations of test
results.

Storage conditions







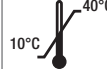
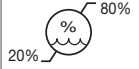


It is important to store the indicator strips in accordance with the storage
conditions as displayed on the box label.

Reference of color change of BD Helix test



Explanation of the color reference

Position 1: Untreated indicator strip (original chemical indicator color)
Position 2: Low temperature / short holding time or absence of steam
Position 3: Typical for vacuum or leakage problem
Position 4: Typical for inert gas problem
Position 5: Complete successful color change

Symbols					
	Consult instructions for use		Expiration date		Date of manufacture
	Keep in a cool, dry place		Keep away from sunlight		Caution: read instructions (warnings) carefully
	Store between 10 and 40°C		Moisture limitation		
	Product code		Lot number		

REF 35951

Importato e distribuito da / Imported and distributed by:
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