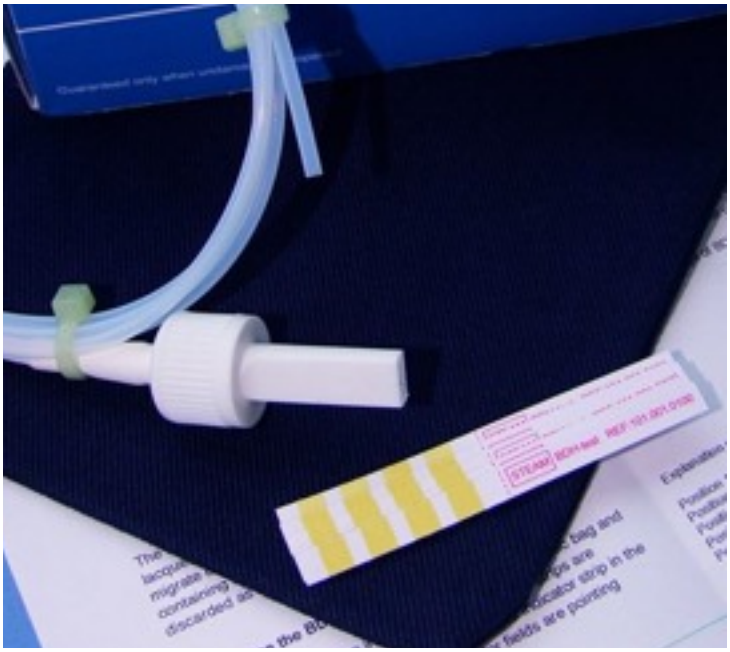
Technical Data Sheet

Product name:

Bowie Dick Helix Test



Product reference:

- ☑ 101.001.0100 STEAM 134ºC - 3,5 min
- ☑ 101.002.0250 STEAM 134ºC - 3,5 min

Applicable standards:

- ☑ ISO 11140 - 1 & 4
- ☑ EN 867 - 5
- ☑ EN 285 + A2 2009
- ☑ EN 13060 + A2 2010
- ☑ EN 980
- ☑ ISO 9001 / ISO 13485

Content:

Attachment(s):

- ☑ A Certificate of conformity
- ☑ B Dimensional and material data Helix Device

SP Medikal San. Ltd. Şti.
Topçular Mah. İncirlik Sok. Ertaş İş Merkezi
No:5/65 Kat:2 Rami/Eyüp-İstanbul-TÜRKİYE
VAT: Rami- 781 046 3595

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(US$) Account No. : 9089602
(EUR) Account No. : 9089601

BIC : TGBATRIS Branch No.: 437
IBAN: TR09 0006 2000 4370 0009 0896 02
IBAN: TR36 0006 2000 4370 0009 0896 01

1 Introduction

The Helix Test as Bowie Dick Test has been introduced first for small Bench Top Steam Sterilizers class B by the EN 867- 5 standard. Based upon a batch control Helix device from the old days for Formaldehyde sterilizers it consists out of a Helix Device type 'Hollow A' made of Teflon and with a 1,5 mtr long Teflon tube.

In 2009 however after years of debate and discussions this same Helix Device was written into the EN 285 standard under Amendment A2. This was done after various institutes such as the Dutch RIVM and the German Robert Koch Institute recommended the use of Helix devices in all cycles.

The EN 285 + Amendment A2: 2009 are specifying the Helix test (Hollow A) to be used as Bowie Dick Test when hospitals are sterilizing Hollow Loads.

Next to that this Bowie Dick Helix Test is an obligatory test for class B Bench Top Steam sterilizers as per EN 13060 + A2 2010

2 Description

The BDHT consists out of a Chemical Indicator Holder in Teflon connected to a 1,5 mtr long tube. This type of Bowie Dick Test is early detecting failures during the Bowie Dick Test cycles as it detect smaller volumes of trapped air etc. Failures which are picked-up by the BDHT are:

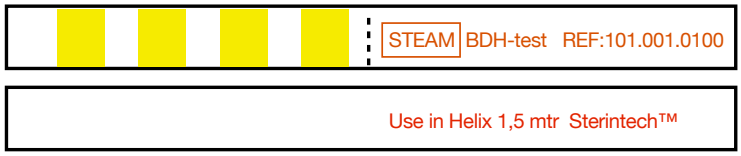
✦- Sterilization temperature too low
✦- Sterilization holding time too short
✦- Insufficient vacuum in depth and in number of vacuum pulses.
✦- Insufficient air removal from hollow devices
✦- Insufficient steam penetration in hollow devices
✦- Leakage of piping / valves / door seals
✦- Detection of presence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

The BDHT is consisting out of the following items:

- 1 piece of Helix device (Teflon with 1,5 mtr long tube)
- 100 (or 250) pieces of Chemical indicator strips ISO 11140 - Class 2 with adhesive on the back
- 1 piece of Cotton bag
- 1 piece of Direction For Use (DFU) with color change images
- 1 piece of Carton

Each chemical indicator strip is 6 mm wide and 76 mm long. For lay-out of both front and back of the chemical indicator strip pls refer to the following page.

Lay-out:



3 Confirmation to standards

The Sterintech™ BDHT are compliant to the following standards:

Helix:	EN 285 :2005 + Amendment A2 : 2009 EN 867 - part 5
Chemical Indicator:	ISO 11140 part 1 : 2005 ISO 11140 part 4 : 2007 - Class 2

Pls refer to the attached Certificate of Conformity.

CIER Vessel results

The indicator strips have been undergoing CIER Vessel testing. Test results are shown at the right in the picture.

Important is that the indicator strip should have start to develop but not reaching end color at 2.14 minutes.

Next to that the indicator strip should reach full end color (black in this case) at 3,5 minutes of exposure to 134 degrees Celsius.

These results were obtained by preliminary testing of the actual product. Based upon these test further testing were conducted with the first lot being produced.

SP Medikal San. Ltd. Şti.
Topçular Mah. İncirlik Sok. Ertaş İş Merkezi
No:5/65 Kat:2 Rami/Eyüp-İstanbul-TÜRKİYE
VAT: Rami- 781 046 3595

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(US$) Account No. : 9089602
(EUR) Account No. : 9089601

BIC : TGBATRIS Branch No.: 437
IBAN: TR09 0006 2000 4370 0009 0896 02
IBAN: TR36 0006 2000 4370 0009 0896 01

Test results including Helix and Indicator strip placed inside cotton bag

This is strip is showing the result of Dry Heat test at 140 degrees Celsius for 30 minutes. There is hardly any color change visible.

This strip is showing the result of a normal 134 degrees Celsius - 3,5 minutes BD test program at which vacuum is not working.

This strip is the result of a normal 134 degrees Celsius - 3,5 minutes BD test program at which only 2 vacuum pulses were programmed.

This strip is showing the result of a normal normal 134 degrees Celsius - 3,5 minutes BD test program.

These results were obtained during our testing in July 2011 with the first lot which had been produced based upon specific BD cycle parameters. For more details you may request us additional information.

SP Medikal San. Ltd. Şti.
Topçular Mah. İncirlik Sok. Ertaş İş Merkezi
No:5/65 Kat:2 Rami/Eyüp-İstanbul-TÜRKİYE
VAT: Rami- 781 046 3595

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(US$) Account No. : 9089602
(EUR) Account No. : 9089601

BIC : TGBATRIS Branch No.: 437
IBAN: TR09 0006 2000 4370 0009 0896 02
IBAN: TR36 0006 2000 4370 0009 0896 01

4 Raw Materials

The Sterintech™ BDHT are consisting out of the following materials:

Helix:	See Attachment B	
Cotton bag:	100% Natural cotton, Blue	
Indicator strip:	Paper	Blanc wood free offset satinated paper
	Indicator Ink,	Waterbased, non solvent, non-toxic, non-heavy metals
	Lacquer:	Waterbased, non solvent, non-toxic
Plastic bag:	LD-PE - fully recyclable	
Box:	Carton, dim.: 170 x 120 x 55 mm (LxWxH)	
Box Label:	Vellum and acrylic glue, no natural latex	
Manual:	90 gr/m2 paper	

5 Quality assurance

The Sterintech™ BDHT are produced in accordance with our ISO 13485 based procedures. All working instructions and checking methods are laid-down in our Quality Assurance system which is audited twice a year internally and once year by external auditors.

All products produced by SP Medikal are traceable by lot numbers. Production files are recorded and kept for 10 years and by these every product can be traced and linked to raw materials used for the production of the product.

Re-call procedures are in forming a part of our quality manual.

6 Packaging

The Sterintech™ BDHT packed in a standard carton box as specified under 4) Raw Materials with the following dimensions: 170 x 120 x 55 mm (L x W x H)

7 Storage conditions

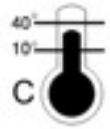
On each box the storage conditions are mentioned which guarantees the product specifications within the expiry time. Claims of non-performance of the product are subject to registered storage conditions. SP Medikal is guaranteeing the performance of the products within the specified Expiry time unless the packaging was opened or damaged.

8 Explanation of Symbols

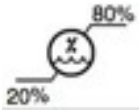
The following storage conditions symbols (EN 980) are used on the box:

Keep dry and away from fluids

Protect against UV light



Store at specified temperatures



Store at specified relative humidity

9 Manufacturer’s declaration

Interfering substances or conditions and release of toxic substances.

On this date there are no known interfering substances or conditions that are affecting the performance of the indicators as long as they are stored as per required storage conditions.

To the best of our knowledge there are no bleeding / staining effects or releases of toxic substances in the quantities which can cause a health hazard or hazard to the goods during sterilization.

The BDHT are produced in a climate controlled production room which has been designed based upon the GMP guidelines at the following location by:

SP Medikal San Ltd. Sti.
Topçular Mahallesi
Incirlik Sokak
Ertas Is Merkezi , No.: 5/65 Kat : 2
Rami / Eyüp Istanbul
Turkey

Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Bowie Dick Helix Tests (BDHT) with:

- REF.: 101.001.0100 STEAM 134ºC - 3,5 min
- REF.: 101.002.0250 STEAM 134ºC - 3,5 min

have been tested in a CIER-Vessel at an independent Laboratory based upon the requirements as per ISO 11140 part 1 and 4.

We herewith confirm that the BDHT's are designed and compliant to the following standard:

Helix:

EN 285, 2005 + A2, 2009:
'Sterilization Steam Sterilizers, Large Sterilizers'

EN 13060:2004+A2:2010
Small steam sterilizers

EN 867 - part 5, 2001 :
'Non-biological systems for use in sterilizers. Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S'

Chemical Indicator:

ISO 11140 - part 1, 2005:
'Sterilization of health care products
Chemical indicators -- Part 1: General requirements'

ISO 11140 - part 4, 2007:
'Sterilization of health care products -- Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration'

Based upon these tests the chemical indicator is classified as class 2

20th February 2014

Seda Kücükyilmaz
Quality Department

Peter M. den Uil (B. Sc.)
Managing Partner

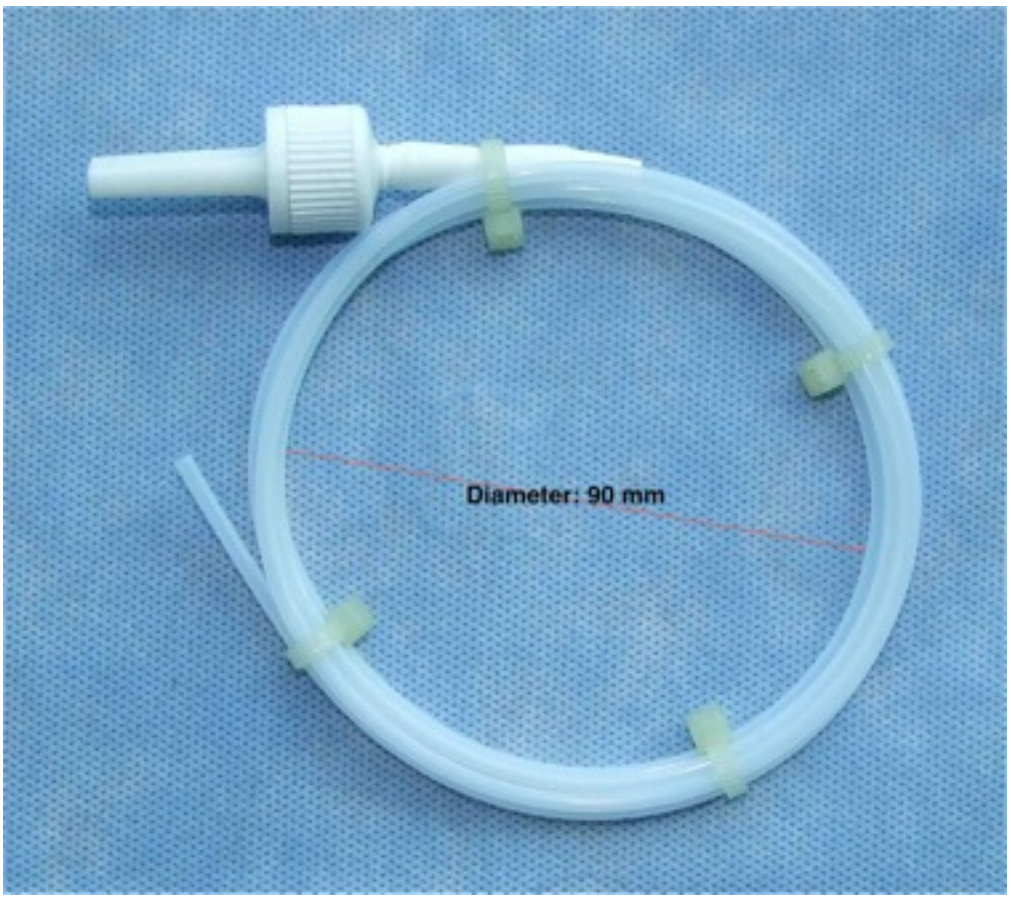
SP Medikal San. Ltd. Şti.
Topçular Mah. İncirlik Sok. Ertaş İş Merkezi
No:5/65 Kat:2 Rami/Eyüp-İstanbul-TÜRKİYE
VAT: Rami- 781 046 3595

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(US$) Account No. : 9089602
(EUR) Account No. : 9089601

BIC : TGBATRIS Branch No.: 437
IBAN: TR09 0006 2000 4370 0009 0896 02
IBAN: TR36 0006 2000 4370 0009 0896 01

B Dimensional data Helix Device



Helix

Indicator holder:	Polypropylene, white (melting point > 175°C) Dimensions: Company Confidential
Tube:	100% PTFE Virgin, Natural color, ASTM D3295 compliant Length: 1.5 mtr, ID: 2 mm, OD: 3 mm.
Sealing ring:	Silicon FDA rot (-60 - +220°C) 8 mm – internal diameter
Shrink Sleeve:	PTFE , (-55°C - + 195°C) 6 mm Internal diameter. – 40 mm length
Cable Binders:	High Temperature Resistant > 150°C for 5.000 hours Color: Natural, Material: Polyamid 4.6 Dimensions: 100 x 2,5 mm