Product group: Sterican®

Index:

1	**SCOPE**	**2**
2	**INTENDED USE**	**3**
3	**PRODUCT DESCRIPTION**	**3**
	3.1 Exploded Assembly Drawing	**3**
	3.2 List of Materials	**4**
	3.3 Basic Product Characteristics	**4**
	3.4 Packaging	**5**
	3.5 Protective Cap	**5**
	3.6 Sterican® Cannula	**5**
	3.7 Sterican® Plastic Hub	**5**
4	**PRODUCT CLASSIFICATION**	**5**
5	**GENERAL REQUIREMENTS**	**6**
6	**STERILISATION METHOD**	**6**
7	**PROPERTIES**	**7**
8	**DOCUMENT ADMINISTRATION**	**8**
	8.1 Amendment Information	**8**

This document contains information that is the confidential and proprietary property of B. Braun. Any dissemination, distribution or copying of this document is strictly prohibited without the prior written consent of B. Braun. Anyone receiving this document in error should immediately notify B. Braun's Legal Department and return this document to B.Braun. Viewed by:janskide

Product group: Sterican®

1 Scope

The product specification applies to the following products:

B|Braun Code Number	Designation (Product Description)	Outer Ø		Cannula Length		Plastic Hub Colour
		Gauge	mm	mm	inch	
4656300	Sterican® 0.30 x 12mm	30	0.30	12	½	Yellow
4665406	Sterican® 0.40 x 12mm	27	0.40	12	½	Grey
4660072	Sterican® 0.40 x 12mm	27	0.40	12	½	Grey
4657705	Sterican® 0.40 x 20mm	27	0.40	20	¾	Grey
9186174	Sterican® 0.40 x 25mm	27	0.40	25	1	Grey
9180117	Sterican® 0.40 x 25mm	27	0.40	25	1	Grey
9186182	Sterican® 0.40 x 40mm	27	0.40	40	1½	Grey
4665457	Sterican® 0.45 x 12mm	26	0.45	12	½	Brown
4053665	Sterican® 0.45 x 12mm KKM	26	0.45	12	½	Brown
4657683	Sterican® 0.45 x 25mm	26	0.45	25	1	Brown
4053666	Sterican® 0.45 x 25mm KKM	26	0.45	25	1	Brown
4657853	Sterican® 0.50 x 16mm	25	0.50	16	5/8	Orange
9186158	Sterican® 0.50 x 25mm	25	0.50	25	1	Orange
4053630	Sterican® 0.50 x 25mm KKM	25	0.50	25	1	Orange
9186166	Sterican® 0.50 x 40mm	25	0.50	40	1½	Orange
4657675	Sterican® 0.55 x 25mm	24	0.55	25	1	Lilac
4053621	Sterican® 0.55 x 25mm KKM	24	0.55	25	1	Lilac
4657667	Sterican 0.60 x 25mm	23	0.60	25	1	Blue
4053605	Sterican® 0.60 x 25mm KKM	23	0.60	25	1	Blue
4657640	Sterican® 0.60 x 30mm	23	0.60	30	¼	Blue
4053613	Sterican® 0.60 x 30mm KKM	23	0.60	30	1¼	Blue
4666410	Sterican® 0.60 x 40mm	23	0.60	40	1½	Blue
4665600	Sterican® 0.60 x 60mm	23	0.60	60	2⅜	Blue
4665635	Sterican® 0.60 x 80mm	23	0.60	80	3	Blue
4657624	Sterican® 0.70 x 30mm	22	0.70	30	1¼	Black
4660021	Sterican® 0.70 x 40mm	22	0.70	40	1½	Black
4053648	Sterican® 0.70 x 40mm KKM	22	0.70	40	1½	Black
4650018	Sterican® 0.70 x 50mm	22	0.70	50	2	Black
9180109	Sterican® 0.80 x 22mm	21	0.80	22	7/8	Green
4657543	Sterican® 0.80 x 25mm	21	0.80	25	1	Green
4053664	Sterican® 0.80 x 40mm KKM	21	0.80	40	1½	Green
4665465	Sterican® 0.80 x 80mm	21	0.80	80	3	Green
4665643	Sterican® 0.80 x 120mm	21	0.80	120	4½	Green
4657527	Sterican® 0.80 x 40mm	21	0.80	40	1½	Green
4665503	Sterican® 0.80 x 50mm	21	0.80	50	2	Green
4657500	Sterican® 0.90 x 25mm	20	0.90	25	1	Yellow
4657519	Sterican® 0.90 x 40mm	20	0.90	40	1½	Yellow

Effective

Product group: Sterican®

4667093	Sterican® 0.90 x 50mm	20	0.90	50	2	Yellow
4665791	Sterican® 0.90 x 70mm	20	0.90	70	2¾	Yellow
4665317	Sterican® 1.10 x 30mm	19	1.10	30	1¼	Ivory
4657799	Sterican® 1.10 x 40mm	19	1.10	40	1½	Ivory
4665112	Sterican® 1.10 x 40mm	19	1.10	40	1½	Ivory
4053656	Sterican® 1.10 x 40mm KKM	19	1.10	40	1½	Ivory
4665511	Sterican® 1.10 x 50mm	19	1.10	50	2	Ivory
4650034	Sterican® 1.20 x 40mm	18	1.20	40	1½	Pink
4665120	Sterican® 1.20 x 40mm	18	1.20	40	1½	Pink
4667123	Sterican® 1.20 x 50mm	18	1.20	50	2	Pink
4665473	Sterican® 2.10 x 80mm	14	2.10	80	3	Pale Green

2 Intended use

Hypodermic needle

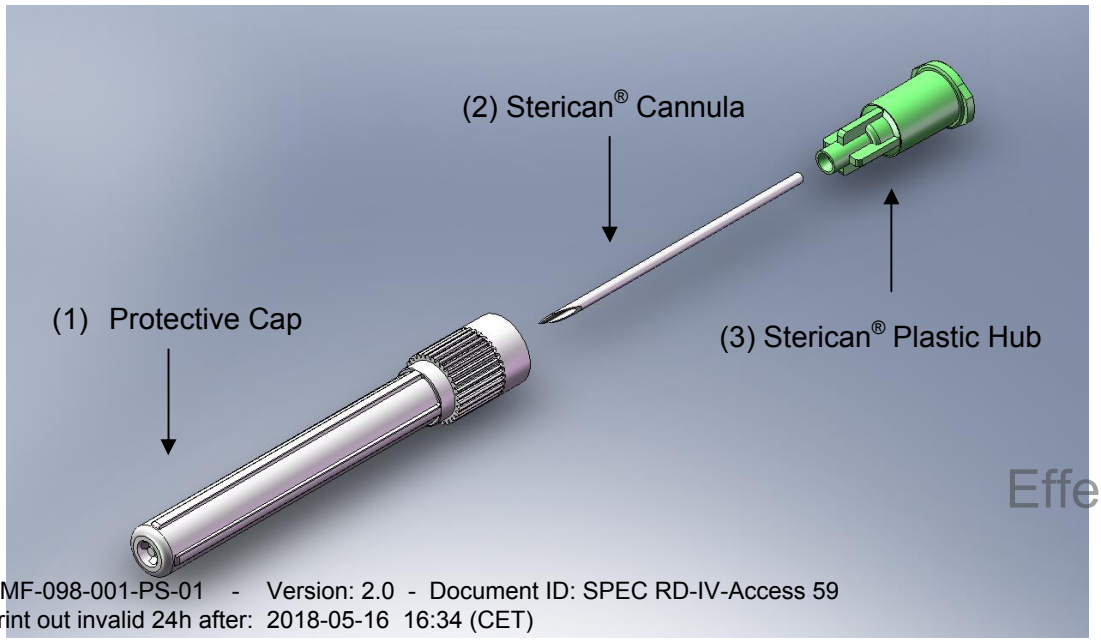
Blood sampling, intravenous injection, subcutaneous injection, intramuscular injection, joint and soft tissue injection, fine needle aspiration, intravitreal injection

3 Product description

Sterican® hypodermic needles are used in the long established and proven manner together with a syringe for percutaneous puncture of blood vessels, either for the purpose of injections or blood sampling, injections into muscle tissue and other professionally required procedures.

The colour coded hub can be used to establish either slip fit or locking type connections to male 6 % (Luer) taper slip fit or locking type adapters.

3.1 Exploded Assembly Drawing



Product group: Sterican®

3.2 List of Materials

	Designation		Description
1	Protective Cap	PP / PE-HD*	Polyprophylene / Polyethylene, high density
2	Sterican® Cannula	- - -	Stainless Steel
3	Sterican® Plastic Hub	PP	Polyprophylene
4	Adhesive	---	UV-curing Adhesive / Epoxy Glue
5	Lubricant	---	Silicone Oil
6	Single Peel Pack	Uncoated Paper Transparent & Un-powdered	Medical Grade Paper
7	Container box	Cardboard box with label	Duplex
8	Transport / multi-package box	With label	Double wall corrugated paper

* : gauges 18G to 27G and lengths from ¾" to 4 ¾"

3.3 Basic Product Characteristics

Feature	Remarks
Type of connection	Female luer – lock connector
Compatibility	Compatible to male luer lock and luer slip connector
Type of sterilisation (exclusive bulk version)	Ethylene Oxide (ETO)
Shelf life	5 years
Storage requirements	Store in a dry place at room temperature and protect from light
Transportation requirements	No specific transport requirements
Hypoallergenic	DEHP free
	Latex free
Cannula bevel geometry	Front cut bevel
Gauge sizes	30G (Yellow), 27G (Grey), 26G (Brown), 25G (Orange), 24G (Lilac), 23G (Blue), 22G (Black), 21G (Green), 20G (Yellow), 19G (Ivory), 18G (Pink), 14G (Pale Green)
Hub	Colour coded to represent gauge sizes

Effective

Product group: Sterican®

3.4 Packaging

The packaging shall protect the product against contamination and mechanical damages.

Primary packaging	Single blister pack designated as a microbiological barrier to assure the sterility of the product.
Duplex box (dispenser)	Container box containing a defined quantity of primary packaging. Quantity = 100pcs per box
Carton box	Transport box for dispatching and additional protection against mechanical damages during transportation. Quantity = 1000pcs per carton (10 duplex boxes)

3.5 Protective Cap

The protective cap covers the cannula over its total length against mechanical impacts when unpacked immediately prior to use.

3.6 Sterican® Cannula

A steel cannula with front-cut bevel configuration is used to puncture the appropriate blood vessel. The bevel geometry allows to facilitate easy and low pain penetration of the skin with minimum of puncture force and less traumatic reactions.

3.7 Sterican® Plastic Hub

The luer lock hub comprises female 6% luer taper and threads according to ISO 594-1/2 for enables the fixation on male luer lock & luer slip cone of a syringe. Hub is colour coded according to ISO 6009 and indicates the needle gauge size.

4 Product Classification

According to Directive 93/42/EEC, annex IX, rule 6 the products are classified as Medical Devices Class IIa.

GMDN code : 59230
GMDN identification : Hypodermic needle, single-use, sterile

UMDNS code : 10-561
UMDNS identification : Cannulas

Effective

Product group: Sterican®

5 General Requirements

The products have to conform with the below mentioned standards, valid at the time of manufacturing.

Applicable Standards	
Physical-technical Requirements	
ISO 7864	Sterile hypodermic needles for single use
ISO 594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
ISO 594-2	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
ISO 6009	Hypodermic needles for single use – Color coding for identification
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
Chemical Requirements	
ISO/TR 15510:1997	Stainless steel – Chemical composition
Biological Requirements	
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
Miscellaneous	
ISO 14971	Medical devices – Application of risk management to medical devices
EN 556	Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.
EN 868-1	Packaging materials and systems for medical devices which are to be sterilized. General requirements and test methods.
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN 1041	Information supplied by the manufacturer with medical devices.
ISO 11135-1	Sterilization of healthcare products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11737	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in definition, validation and maintenance of a sterilization process.
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.

6 Sterilisation Method

The products are sterilized by Ethylene Oxide (EO).

Effective

Product group: Sterican®

7 Properties

Visual Characteristics	Standard
Colour coding	ISO 6009
Packaging	ISO 7864
Labelling	ISO 7864
Cleanliness	ISO 7864
Siliconization	ISO 7864
Tightness Characteristics	
Air-tightness peel packaging	-
Tensile Strength	
Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88-00
Particulate Contamination Characteristics	
Absence of particles	ISO 7864
Function Characteristics	
Peelability	-
Stiffness cannula	ISO 9626
Piercing force	-
Dimensional Accuracy Characteristics	
Luer lock connection	ISO 594-1/2
Cannula length	ISO 7864
Cannula diameter (inner / outer)	ISO 9626
Bevel geometry	ISO 7864
Chemical Characteristics	
Resistance to corrosion	ISO 9626
Biological Characteristics	
Haemolytic	ISO 10993-1
Free of bacterial endotoxins	ISO 10993-1
Non toxic	ISO 10993-1
Pyrogen free	ISO 8536-4
Free of particulate contamination	ISO 10993-1
Sterile	ISO 11135-1

– End of document –

Effective

Product group: Sterican®

8 Document Administration

8.1 Amendment Information

Version	Description of the changes
1.0	Creation of document
2.0	Addition of applicable product with article no. 4656300. Correction for list materials from coated paper to uncoated paper. Change in GMDN code and GMDN identification. Update on the applicable standards.

Effective

Title: Sterican Initiator: Lay Hooi . Ang

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Frank Viermann (vierfrmy)
Title: BMI-RD-Senior Manager
Date: Wednesday, 11 September 2013, 09:56 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Ulrich Jedelhauser (jedeulde)
Title: Manager Regulatory Affairs CoE IV-Systems / CoE IV Access
Date: Wednesday, 11 September 2013, 14:25 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Hermann Riesenberger (rieshede)
Title: HC-RD-DE08E Head of RD IV Access
Date: Wednesday, 11 September 2013, 21:43 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Thomas Moeller (moelthmy)
Title: General Manager QM, QC and RA
Date: Thursday, 12 September 2013, 06:12 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective