Product group: Stopper – Cones - Adapter

Index:

1	SCOPE	3
2	INTENDED USE	3
2.1	Combi-Stopper	3
2.2	IN-Stopper	3
2.3	Combifix® Adapter	3
2.4	Stopper	3
2.5	Connecting Piece w/ lease lock nut	3
2.6	Discofix® Closing Cone	4
3	PRODUCT DESCRIPTION	4
3.1	Description	4
3.1.1	Combi-Stopper	4
3.1.2	IN-Stopper	4
3.1.3	Combifix® Adapter	4
3.1.4	Stopper	4
3.1.5	Connecting Piece w/ lease lock nut	4
3.1.6	Discofix® Closing Cone	4
3.2	Exploded assembly drawing	5
3.2.1	Combi-Stopper	5
3.2.2	IN-Stopper	5
3.2.3	Combifix® Adapter	5
3.2.4	Stopper	5
3.2.5	Connecting Piece w/ lease lock nut	6
3.2.6	Discofix® Closing Cone	6
3.3	Materials	6
3.4	Basic product characteristics	7
3.5	Packaging	7
3.6	All components / complete set	7
3.7	Luer lock connections	7
3.8	Injection port	7
3.9	Record adapter	8
4	PRODUCT CLASSIFICATION	8
4.1.1	Combi-Stopper	8
4.1.2	IN-Stopper	8
4.1.3	Combifix® Adapter	8
4.1.4	Stopper	8

Effective

Reference: SOP HC-DDDD-M-5-2-04-536 Preparation of product- and test specifications

Product group: Stopper – Cones - Adapter

4.1.5 Connecting Piece w/ lease lock nut 8
4.1.6 Discofix® Closing Cone 8
5 GENERAL REQUIREMENTS 9
6 STERILISATION METHOD 10
7 PROPERTIES 11
8 APPENDICES 12
9 DOCUMENT ADMINISTRATION 13
9.1 Amendment information 13

Product group: Stopper – Cones - Adapter

1 Scope

The Product specification applies for the following products:

- Combi-Stopper
- IN-Stopper
- Combifix® Adapter
- Stopper
- Connecting Piece w/ lease lock nut
- Discofix® Closing cone

Art. No.	Designation	characteristics
4495101	Combi-Stopper	red
4495101R	Combi-Stopper	red
4495152	Combi-Stopper	blue
4495152B	Combi-Stopper	blue
4495209	Combi-Stopper	white
4495102	Combi-Stopper	purple
4238010	IN-Stopper	inject port/male
4238011	IN-Stopper (local)	inject port/male
4090306	Combifix®-Adapter	female/record
5206634	Combifix®-Adapter	female/female
5206642	Combifix®-Adapter	male/male
4097076	Stopper	male
4090705	Connecting Piece w/ lease lock nut	male/male
4597982	Discofix® Closing cone	male

2 Intended use

2.1 Combi-Stopper

Closing cones, Luer Lock fitting male and female

2.2 IN-Stopper

Male Luer Lock Closing cone with injection port for intermittent injections through injection membrane

2.3 Combifix® Adapter

Adapters for Interconnection of Male and Female Fittings with 6 % (Luer) and 10 % (Rekord) Taper Fittings

2.4 Stopper

Male Luer Lock Closing cone

2.5 Connecting Piece w/ lease lock nut

Male/male Luer Lock connector with swivel Lock

Effective

Product group: Stopper – Cones - Adapter

2.6 Discofix® Closing Cone

Male Luer Lock Closing cone

3 Product description

3.1 Description

3.1.1 Combi-Stopper

- Luer Lock fitting male and female
- Made of PE (Polyethylene)
- Available in red, blue and white for the field of IV-therapy, available in purple for the field of enteral nutrition
- Sterile closing of all kinds of open luer accesses
- Sterile closing of pre-filled syringes

3.1.2 IN-Stopper

IN-Stoppers, easy and convenient in handling, close needle-free injection sites and offer a needle access via a latexfree membrane. Can also be used as closing cones for female accesses

- Smooth, hygienic outer surface
- Contact-free Luer taper
- Priming volume 0.16 ml
- Latex-free

3.1.3 Combifix® Adapter

These slip fit type adapters are one-component injection moulded parts to be used in combination with and interconnection of corresponding male and female 6 % and 10 % taper fittings in equipment routinely used in medical devices such as infusion sets, transfusion sets, catheters, needles, syringes, extension fluid lines, fluid line systems, connectors and the like.

3.1.4 Stopper

Stopper are universally used to close needle-free injection sites.

3.1.5 Connecting Piece w/ lease lock nut

This product is used for the connection of male/male devices. The swivel lock enables a tight luer lock connection with other medical products

3.1.6 Discofix® Closing Cone

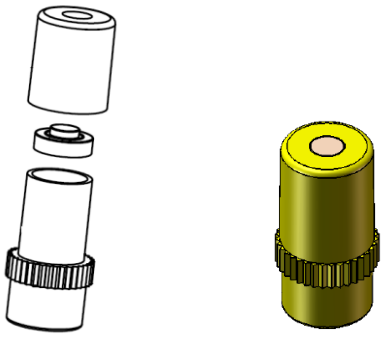
This Article cone is used to close Discofix® stopcocks.

Product group: Stopper – Cones - Adapter

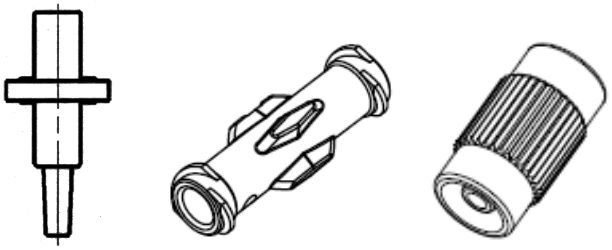
3.2 Exploded assembly drawing

3.2.1 Combi-Stopper

3.2.2 IN-Stopper



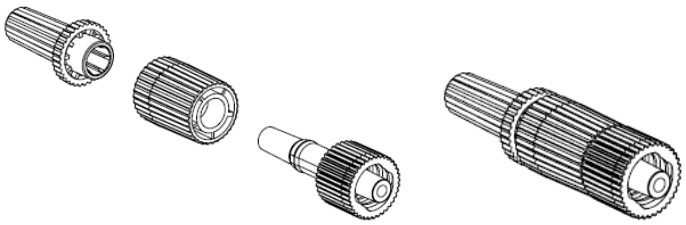
3.2.3 Combifix® Adapter



3.2.4 Stopper

Product group: Stopper – Cones - Adapter

3.2.5 Connecting Piece w/ lease lock nut



3.2.6 Discofix® Closing Cone

3.3 Materials

Individual components	Material	
Combi-Stopper	Polyethylene + a coloured masterbatch	PE
IN-Stopper		
Housing	Acrylonitrile-butadiene-styrene-plastic	ABS
Latex Disc	Isoprene rubber, synthetic	IR
Protective Cap	Acrylonitrile-butadiene-styrene-plastic	ABS
Combifix Adapter		
male/male	Methylmethacrylate-acrylonitrile-butadiene-styrene	MABS
female/female	Methylmethacrylate-acrylonitrile-butadiene-styrene	MABS
record/luer	Methylmethacrylate-acrylonitrile-butadiene-styrene	MABS
Stopper	Polyethylene	PE
Connecting Piece w/ lease lock nut		
connecting piece	Polycarbonate	PC
collar	Polycarbonate	PC
protective cap	Polypropylene	PP

Effective

Product group: Stopper – Cones - Adapter

Discofix Closing Cone	Polypropylene	PP
Packaging material		
Paper	paper	paper
Film	polyamide/polyethylene	PA/PE

3.4 Basic product characteristics

Features	**Notes**
Type of connection	luer and luer lock connection (and piercing device (IN-Stopper))
Packaging	single sterile packed
Sterile	ETO or Radiation (Gamma)
Shelf life	3 years or 5 years
Safety feature	lock mechanism
Hypoallergenic	latex-free
	PVC-free
	DEHP-free
	no animal by-product materials

3.5 Packaging

Primary Packaging:	Individual single peel pack designated as a microbiological barrier to assure the sterility of the product.
Multi Packaging (dispenser box):	Container box containing a certain number of primary packaging.
Transport Packaging (shipping box)	Shipping box for dispatching and additional protection against mechanical damages during transportation.

3.6 All components / complete set

Stoppers and Cones are used to close a luer or luer lock access on other devices
Adapters are used to connect female luer connections to other female connections or male luer connection to other male luer connections or male luer connections to record female connections.

3.7 Luer lock connections

The luer lock connection is used to connect the device to other luer and luer lock devices.

3.8 Injection port

Effective

Product group: Stopper – Cones - Adapter

The cannula bounded Injection port is used to offer a needle access via a latexfree membrane e.g. to an infusion solution.

3.9 Record adapter

The record adapter is used to connect male luer connections to record female connections.

4 Product classification

4.1.1 Combi-Stopper

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class IIa, rule 2.
GMDN Code: 35384; GMDN Designation: Adapter, syringe/needle
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

4.1.2 IN-Stopper

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class IIa, rule 2.
GMDN Code: 35384; GMDN Designation: Adapter, syringe/needle
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

4.1.3 Combifix® Adapter

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class IIa, rule 2.
GMDN Code: 35075; GMDN Designation: Adapter, luer
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

4.1.4 Stopper

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class I sterile, rule 1.
GMDN Code: 16825; GMDN Designation: Syringe tip cap
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

4.1.5 Connecting Piece w/ lease lock nut

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class IIa, rule 2.
GMDN Code: 42988; GMDN Designation: Tubing connector
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

4.1.6 Discofix® Closing Cone

CE: The products are classified as non-active medical device according to Council Directive 93/42/EEC Annex IX, class I sterile, rule 1.
GMDN Code: 16825; GMDN Designation: Syringe tip cap
UMDNS Code: 11-729; UMDNS Designation: Fittings/Adapters, Luer

Effective

Product group: Stopper – Cones - Adapter

5 General requirements

Stopper, Cones, Adapter must conform to the standards in force at the time of manufacture

Packaging/Labeling	
ISO 11607-1:	Packaging for terminally sterilised medical devices– Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
DIN EN 868-2	Packaging for terminally sterilized medical devices Part 2: Sterilization wrap - Requirements and test methods
DIN EN 868-5	Packaging materials and systems for medical devices which are to be sterilized Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
ISO 15223-1:	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
Physical-technical requirements	
ISO 594-1+2:	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements; Part 2: Lock fittings
ISO 8536-10	Infusion equipment for medical use - Part 10 : Accessories for fluid lines for use with pressure infusion equipment
ISO 8536-4	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
Chemical requirements	
ISO 8536-4	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
Biological requirements	
DIN EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
DIN EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 8536-10	Infusion equipment for medical use - Part 10: Accessories for fluid lines for use with pressure infusion equipment

Effective

Product group: Stopper – Cones - Adapter

Sterilization	
ISO 11135	Sterilization of health care products – Ethylene oxide
ISO 11137	Sterilization of health care products – Radiation
EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE”. Part 1: Requirements for terminally sterilized medical devices
DIN 58953-6:	Sterilization - sterile supply Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
Delivery	
The products are supplied in individual sterile packs	
Delivery of the products must comply with the organisation guideline 185/95	
shelf life	
The shelf life is up to 60 months depending on the product	
Conditions of storage	
DIN EN 1041	Information supplied by the manufacturer with medical devices No specific storage conditions Storage as commonly used for medical devices
Conditions of transportation	
DIN EN 1041	Information supplied by the manufacturer with medical devices No specific transportation conditions Transportation as commonly used for medical devices

6 Sterilisation method

The product is gamma or EO sterilized.
The EO Residuals are acc. to DIN EN ISO 10993-7.

Product group: Stopper – Cones - Adapter

7 Properties

Properties	Standard
Tightness	
- Vacuum tightness with p- and g-device	ISO 8536-4+10
- Fluid tightness with p- and g-device	ISO 8536-4+10
- Air tightness with p- and g-device	ISO 8536-4+10
- Vacuum tightness with reference fitting	ISO 594-1+2
- Fluid tightness with reference fitting	ISO 594-1+2
- Fluid tightness injection piece	ISO 8536-4+10
Tensile / pressure strength	
- Tensile strength of all connections	ISO 8536-10
- Separation force from reference fitting	ISO 594-1+2
- Unscrewing torque from reference fitting	ISO 594-1+2
- Resistance to overriding	ISO 594-1+2
- Sealing seam strength, single pack	ISO 11607-1
Visual	
- All packaging stages labelled	ISO 8536-4
- All packaging stages printed	ISO 8536-4
- Device colour acc. to drawing	-
Particulate contamination	
- largely free of particles	ISO 8536-4
Function	
- Ease of assembly	ISO 594-1+2
- Stress cracking resistance	ISO 594-1+2
- Single packaging designed to assure the sterility of the product.	ISO 11607-1
- Closing of all packages	-
- Sealing of single packaging is peelable	DIN EN 868-5
- Avoidance of air bubbles	ISO 8536-10
Dimensional accuracy	
- Conical luer connection	ISO 594-1+2
Chemistry	
- Reducing substances	ISO 8536-4
- Metal ions	ISO 8536-4
- Titration acidity or alkalinity	ISO 8536-4

Effective

Product group: Stopper – Cones - Adapter

Properties	Standard
- Solid residue from evaporation - UV absorption of extraction solution	ISO 8536-4 ISO 8536-4
Biology - Steril - Biocompatible - Pyrogen free - Free from haemolytic reactions	 ISO 11135, ISO 11137 ISO 10993-1 ISO 8536-4+10 ISO 8536-10

8 Appendices

none

– End of document –

Product group: Stopper – Cones - Adapter

9 Document administration

9.1 Amendment information

Version	Description of the changes
1.0	First Issue
2.0	Update due to portfolio enlargement: new Combi-Stopper “purple”
3.0	Added articles 4495101R and 4495152B

Title: Stopper/ Cone/ Adapter - Product Specification Initiator: Jan ? Thieme

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

UserName: Joern, Jens (joerjede)
Title: HC-RD-DE08E - Senior Manager R&D
Date: Friday, 30 June 2017, 15:21 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 03 July 2017, 08:19 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Katerkamp, Andreas (kateande)
Title: HC-RD-DE08E - Head of Development Center IV-Sets/Drug Admixture
Date: Wednesday, 05 July 2017, 16:57 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective