TECHNICAL DATA SHEET

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VASCULAR CATHETERS

CLIP® AUTOMATIC SAFETY I.V. CATHETERS

CLiP® Neo, CLiP® Winged and CLiP® Ported are automatic safety intravenous (I.V.) catheters.

The products have a built-in safety mechanism that encapsulates the tip of the used needle when extracted from the catheter. This prevents accidental needle stick injuries, provided that general effective and safe working procedures and precautions are maintained during use and disposal. The products feature stabilization wings for secure fixation.

The products support compliance with Council Directive 2010/32/EU.

Intended Use

Intravenous/Intravascular access for short-term peripheral cannulation. The use of this product is restricted to qualified healthcare professionals.

Indications

- Infusion of I.V. solutions, including blood & fluids of similar viscosity.
- Intermittent intravenous drug administration.
- Sample blood
- The products withstand use with power injectors rated for a maximum pressure of 21 bar (305 psi).

Contraindications

Product should not be used in patients with known hypersensitivity to any of the materials used.

Product Versions

CLiP® Ported Automatic safety IV catheter

Not made with natural rubber latex and DEHP and PVC free

Product name	Product code FEP material	Product code PUR material	Catheter size	Catheter dimension	Colour code	Catheter flowrate
CLiP® Ported	VP144501	VP144511	14 G	2,0 x 45	orange	290
CLiP® Ported	VP164501	VP164511	16 G	1,7 x 45	grey	200
CLiP® Ported	VP174501	VP174511	17 G	1,5 x 45	white	140
CLiP® Ported	VP184501	VP184511	18 G	1,2 x 45	green	100
CLiP® Ported	VP183201	VP183211*	18 G	1,2 x 32	green	110
CLiP® Ported	VP203201	VP203211*	20 G	1,0 x 32	pink	64
CLiP® Ported	VP202501	VP202511	20 G	1,0 x 25	pink	68
CLiP® Ported	VP222501	VP222511*	22 G	0,8 x 25	blue	38
CLiP® Ported	VP241901	VP241911	24 G	0,7 x 19 (notch)	yellow	22

* Updated unit pack (MDR)

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CLiP® Neo Automatic safety IV catheter

Not made with natural rubber latex and DEHP and PVC free

Product name	Product code FEP material	Catheter size	Catheter dimension	Colour code	Catheter flowrate
CLiP® Neo	NW241901*	24 G	0.7 x 19 (notch)	yellow	22
CLiP® Neo	NW261901*	26 G	0.6 x 19 (notch)	violet	15

* Updated unit pack (MDR)

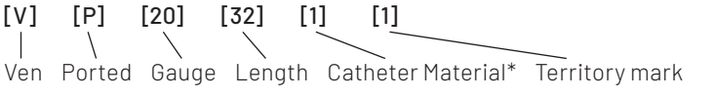
CLiP® Winged Automatic safety IV catheter

Not made with natural rubber latex and DEHP and PVC free

Product name	Product code FEP material	Product code PUR material	Catheter size	Catheter dimension	Colour code	Catheter flowrate
CLiP® Winged	VW144501	VW144511	14 G	2,0 x 45	orange	290
CLiP® Winged	VW164501	VW164511	16 G	1,7 x 45	grey	200
CLiP® Winged	VW174501	VW174511	17 G	1,5 x 45	white	140
CLiP® Winged	VW184501	VW184511	18 G	1,2 x 45	green	100
CLiP® Winged	VW183201	VW183211	18 G	1,2 x 32	green	110
CLiP® Winged	VW203201	VW203211*	20 G	1,0 x 32	pink	64
CLiP® Winged	VW222501	VW222511*	22 G	0,8 x 25	blue	38
CLiP® Winged	-	VW241911	24 G	0,7 x 19	yellow	22

* Updated unit pack (MDR)

Item Reverence



* Catheter Material: 0 = Fluorinated ethylene propylene (FEP) / Catheter Material: 1 = Polyurethane (PUR)

Packaging Characteristics

CLiP®
14 Gauge - 22 Gauge

	Shipping Box Outer	Shipping Box Inner	Shelf Box	Single Package
Units	1000	500	50	1(sterile)
Length (mm)	715	693	150	134
Width (mm)	320	310	95	265
Height (mm)	240	108	135	19
Weight (g)	8200 - 9200*	3300 - 3700*	220 - 278*	4.0 - 4.9*

*depending on Gauge size and length

CLiP®
24 Gauge - 26 Gauge

	Shipping Box Outer	Shipping Box Inner	Shelf Box	Single Package
Units	1000	500	50	1(sterile)
Length (mm)	580	565	170	107
Width (mm)	375	355	95	265
Height (mm)	240	108	110	18
Weight (g)	7800 - 8300*	3000 - 3475*	211 - 234*	3.3 - 3.7*

*depending on Gauge size and length

Legal manufacturer

Vigmed AB
Kungsgatan 6
SE-252 21 Helsingborg, Sweden

Tel: +46 42 28 00 90
E-mail: info@vigmed.com
Internet: www.stick-to-safety.com

Quality and Regulatory

Notified body: Presafe DK, ID0543
EN-ISO 13485:2016, DGM-840
EN-ISO 9001:2015, DGM-840

Notified body: DNV Presafe, ID2460
EC Certificate: 10000374687-PA-NA-DNK
Product classification IIa rule 7 according to annex 9 in MDD 93/42/EEC

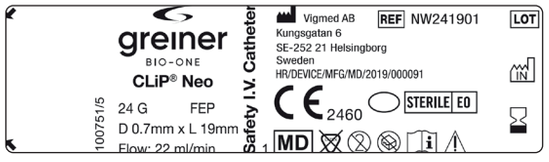
GMDN: 64574

TECHNICAL DATA SHEET

Labeling

Unit Pack:

< MDD compliant unit label used on most products



< MDR compliant unit label currently used on products marked with * in product version overview.

Shelf Box:

Shipper Box:

Packaging Material

Shipper box: corrugated board, 100% reused material
Shelf box: white duplex board
Single unit package: blister in A-PET and Tyvek paper

Symbol Glossary

Symbol	Description
REF	Catalogue number
CC	Date of manufacture and Country of manufacture
	Legal manufacturer
	Use by date
LOT	Batch code
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Caution
LATEX	Not made with natural rubber latex

Symbol	Description
	Keep dry
	Keep away from sunlight
	Do not use if package is damaged
	Consult instructions for use
MD	Medical Device
	Fragile
UDI	Unique Device Identification
	Single sterile barrier system

Note: Printed copies will not systemically be updated. Valid at the date of issue. Information is subject to change.

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Barcode	The bar code on box labels is GS1-128 format; (01) GTiN (17) Expiration date (10) Batch code.
Shelf Life	5 years
Traceability	Full traceability via LOT number
Product Material	Polypropylene (PP), Polycarbonate (PC), Polyethylene (PE), Polyoxymethylene (POM), silicone tubing, silicone oil, stainless steel. Catheter: Fluorinated Ethylene Propylene (FEP) or Polyurethane (PUR) with radiopaque stripes (see item reference, 0 = FEP, 1 = PUR)
Sterilization	Ethylene Oxide
Storing	Store in clean, dry place at room temperature to avoid affecting package/sealing integrity.

Standards and regulations

Identification	Name
LVFS2003:11	Läkemedelsverkets föreskrifter om medicintekniska produkter (Swedish Medicin Agency's regulations on medical devices)
MDD 93/42/EEC	Medical Device Directive
SS-EN ISO 13485:2016	Medical Devices-Quality management systems – Requirements for regulatory purposes
SS-EN ISO 9001:2015	Quality Management Systems – Requirements
SS-EN ISO 23908:2013	Sharps injury protection-Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
SS EN 62366:2016	Medical Devices- Application of usability engineering to medical devices
SS-EN ISO14971:2020	Medical Devices-Application of risk management to medical devices
SS-EN ISO 1 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
SS-EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical device
SS-EN ISO 11135:2014	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of sterilization process for medical devices
SS-EN ISO 10993-1:2018	Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process
SS-EN ISO 10993-3:2014	Biological evaluation of medical devices Part 3:Tests for genotoxicity, carcinogenicity and reproductive toxicity
SS-EN ISO 10993-4:2017	Biological evaluation of medical devices Part 4:Selection of tests for interactions with blood
SS-EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
SS-EN ISO 10993-6:2017	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
SS-EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-7:2008/AC:2009/ AMD 1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – Technical Corrigendum 1(ISO 10993-7:2008/Cor 1:2009) Amendment 1: Applicability of allowable limits for neonates and infants
SS-EN ISO 10993-10:2021	Biological evaluation of medical devices Part 10:Tests for irritation and skin sensitization
SS-EN ISO 10993-11:2018	Biological evaluation of medical devices Part 11:Tests for systemic toxicity
SS-EN ISO 10993-16:2017	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
ASTM D4169 – 16	Standard Practice for Performance Testing of Shipping Containers and Systems

Identification	Name
SS-EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems
SS-EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 9626:2016	Stainless steel needle tubing for manufacture of medical devices – Requirement and test methods
ISO 10555-1:2023	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
ISO 10555-5:2013	Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
MEDDEV 2.7.1 rev. 4: Jun 2016	Guidelines on medical devices CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV 2.12-1 rev. 8: Jan 2013	Guidelines on a medical devices vigilance system
SS-EN 13868:2003	Catheters - test methods for kinking of single lumen catheters and medical tubing
ASTM F88:2021	Standard Test methods for seal strength
SS-EN 868-5:2019	Packaging for terminally sterilized medical devices - Part 5-Sealable pouches and reels of porous materials and plastic film, requirements and test methods
SS-EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile". Part 1 - Requirements for terminally sterilized medical devices.
SS-EN 556-1/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile". Part 1 - Requirements for terminally sterilized medical devices.
ISO 14644-1:2016	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 11138-1:2017	Sterilization of health care products - Biological indicators — Part 1: General requirements
ISO 11138-2:2017	Sterilization of health care products - Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 28590:2017	Sampling procedures for inspection by attributes
ISO 3951-1:2022	Sampling procedures for inspection by variables Part 1: AQL
ISO 7864:2016 (only Annex D test method)	ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods Annex D Test method for measuring the penetration force and drag force for needles