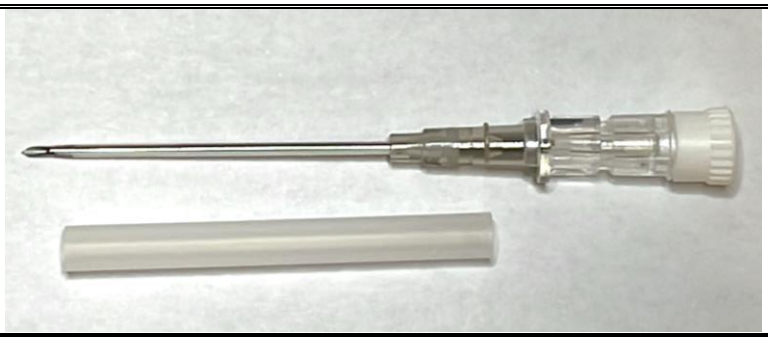
NEO DELTA VEN T	
MANUFACTURER	**Delta Med SpA,** *Via Guido Rossa No. 20 - Viadana (MN) 46019*
INTENDED USE / INDICATIONS	Peripheral IV Catheter for short term peripheral venous access that, in combination with other medical device, allows the administration of fluids. Once placed in the vein, the IV Catheter can be connected to others medical devices to administer therapeutical solutions or drugs. IV Catheters can be connected with others medical devices provided with luer lock or luer fitting connections such as infusion sets, extension lines, stopcocks and syringes. In case of high pressure administration of fluids, like contrast media, the device is connected to extension lines connected to power injectors to administer the contrast media at high pressure. The Catheter can be used on any patient population while taking into account the vascular anatomy of the patient and of the adequacy of the procedure. The catheters are suitable for use with pressure injectors (max. 325psi) **DO NOT USE 26G IV CATHETERS FOR HIGH PRESSURE TREATMENTS.**
DEVICE DESCRIPTION	IV Catheter. Peripheral (cannula needle), consisting of a stainless steel needle, Polyurethane catheter, radiopaque along its entire length, without injection valve and without fastening wings, latex-free.
MD CLASSIFICATION	*Class II a*
CND code	C0101010102

RANGE AND CODES
NEO DELTA VEN T – STANDARD SINGLE WAY IV CATHETER WITHOUT WINGS

Code	Gauge/ Colour	Length (mm)	Outer Dia (mm)	Inner Dia (mm)	Flow (ml/min)	Max pressure psi (*)
3108522	26/ Purple	19	0.64	0.45	19	**N/A**
3118522	24 /yellow	19	0.74	0.55	29	325
3128522	22/blue	25	0.90	0.65	42	325
3138522	20/pink	32	1.00	0.75	59	325
3188522	18/green	32	1.30	0.95	103	325
3148522	18/green	45	1.30	0.95	96	325
3158522	17/white	45	1.50	1.15	155	325
3168522	16/grey	45	1.75	1.35	225	325
3178522	14/orange	45	2.00	1.55	290	325

Note: (*) The indicated pressure refers to the maximum pressure set on the injector.

INFORMATION	
GENERAL FEATURES	Introducer needle with triple-sharpened, atraumatic tip. Polyurethane cannula, radiopaque and tapered to facilitate insertion of the catheter in situ. Fully transparent reflux chamber, designed to promote the best possible visualisation of blood return. Possibility of connection with a syringe already while obtaining intravenous access
RECOMMENDED DWELL TIMES	From a clinical point of view, there is no minimum or maximum dwell time for this type of venous access. The in situ dwell time is established according to local protocols and the procedures of the individual Bodies, also in accordance with the provisions of national and international guidelines. As indicated by the most recent INS and CDC guidelines - if well managed - a venous access of this type can remain in situ as long as clinically indicated, even for longer than 72/96 hours in the absence of site alterations.

PRODUCT FEATURES		
COMPONENT	**MATERIAL**	**FEATURES**
CATHETER (cannula in plastic material)	Polyurethane (PUR)	Flexible catheter tube with tapered open tip, superficially silicone coated as required by the EN ISO 10555-1 standard. Intended to ensure peripheral venous access as it is positioned in superficial peripheral veins.
RX-OPAQUE LINE	Pharmaceutical Barium Sulphate (white) – No. 3 lines. BaSO4	Allows x-ray detectability of the catheter tube when placed into a vein. The radiopaque line is embedded in the PUR material so that no leakage of BaSO4 into the patient's blood is possible
CATHETER BODY	Polypropylene (PP)	Allows the catheter to be correctly fixed to the patient's skin, to be connected to an infusion set for the continuous or intermittent administration of liquids and drugs and to be connected to a syringe as it is equipped with a Luer lock fitting. In accordance with EN ISO 10555-5, the colour of the catheter body distinguishes the diameter of the Gauge for immediate recognition.
INTRODUCER NEEDLE	Stainless steel and ABS	Introducer needle formed by a stainless steel cannula connected to a transparent mandrel. The needle is triple-sharpened – which guarantees atraumatic venous access. The introducer needle complies with the EN ISO 10555-5 standard and allows catheter placement in the vein and, as it is silicone coated, its easy removal.
REFLUX CHAMBER	Acrylonitrile-butadiene-styrene copolymer (abs)	Totally transparent and equipped with a water-repellent filter that allows easy visualisation of the venous return – favouring a correct venous access
PROTECTIVE CAP	Low Density Polyethylene (LDPE)	It ensures the piercing part of the Catheter is protected, avoiding accidental damage
LUER LOCK CAP	Polypropylene (PP)	It allows the temporary suspension of the treatment.

GENERAL PRODUCT AND PRODUCTION INFORMATION	
PACKAGING	The device is packaged in blister packs formed by laminated medical paper welded to the thermoforming film. Each individual package bears the colour code identifying the Gauge of the IV Catheter it contains. The secondary packaging contains 50 pieces and is made of a cellulose material. The carton contains 10 secondary packs, 500 pieces. The primary packaging complies with UNI EN ISO 11607 part 1 and 2.
STERILISATION	Ethylene Oxide. Sterilisation cycle validated in accordance with the UNI EN ISO 11135 standard.
EXPIRY DATE	5 years from the date of sterilisation if the packaging is intact and the device is properly detached. Single-use device, reusing the device can have a negative effect on functionality and sterility with consequences such as device malfunction and contamination.
BIOCOMPATIBILITY	All materials and lubricants are biocompatible according to the ISO 10993 standard.
LABELLING	Present on the blister and on the outside of the packaging. Identification of product identification data in accordance with the directive (93/42/EEC point 13.3) with the specific technical standards (UNI EN ISO 15223-1).
PRODUCTION	Production takes place in a controlled environment. Controls of microbiological contamination of the air and surfaces as well as particle contamination are routinely performed in accordance with the reference technical standards.
TRACEABILITY	Delta Med guarantees complete traceability of the batches produced through the identification of the medical device for each batch assigned.
DISPOSAL	Immediately after its removal, the introducer needle must be disposed of in a special rigid container for the disposal of needles and sharp objects. Disposal must take place in compliance with national, community and international directives on the matter. In any case, current hospital protocols should be followed.
STORAGE	Store in a clean, dry warehouse.
WARNINGS	Follow aseptic techniques. Single-use device. Do not re-sterilise.
PRODUCT CONTROLS	• Incoming control: visual and functional on bulk product and packaging materials. • In-process control: visual inspection of the product and the labelling. • Biological and chemical checks performed every 6 months, such as: Lal, bioburden, sterility, residual ethylene oxide tests and chemical analysis according to EU Pharmacopoeia.
QUALITY SYSTEM AND PRODUCT CERTIFICATIONS	**Quality System in compliance with the standards:** **UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016** **Certification body:** TUV SUD Product Service
	Product certification*:* in compliance with Regulation EU MDR 745/2017and its subsequent modifications and amendments. - **EC Certificate**: **G20 026056 0032 Rev. 00** **Notified Body CE0123: TUV SUD Product Service GmbH**

REFERENCE STANDARDS

- EN ISO 13485:2016/A11.2021 - Harmonized standard - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016).
- EN ISO 14971:2019/A11.2021 - Medical devices - Application of risk management to medical devices
- EN ISO 10993-12:2021. Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- EN ISO 10993-3:2014. Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-4:2017. Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- EN ISO 10993-5:2009. Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-6:2016. Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
- EN ISO 10993-10:2013. Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- EN ISO 10993-11:2018. Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- EN ISO 10555-1: 2013/A1.2017. Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1
- EN ISO 10555-5: 2013. Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
- EN ISO 9626: 2016. Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- EN ISO 80369-7:2017. Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- EN ISO 11135:2014 - Sterilization of health care products – Ethylene Oxide-Part 1 – Requirements for development, validation and routine control of the sterilization process for medical devices
- EN ISO 11607-1:2020- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- EN ISO 11737-1:2018 - Sterilization of health care products - Microbiological methods Determination of a population of microorganisms on products
- EN ISO 11737-2:2020 - Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
- EN ISO 11138-1:2017 - Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
- EN ISO 11138-2:2017 - Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
- EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- EN IEC 62366-1:2015 – Medical device. Part 1 – Application of usability engineering to medical device
- EN ISO 20417:2021. Medical device. Information to be supplied by the manufacturer

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