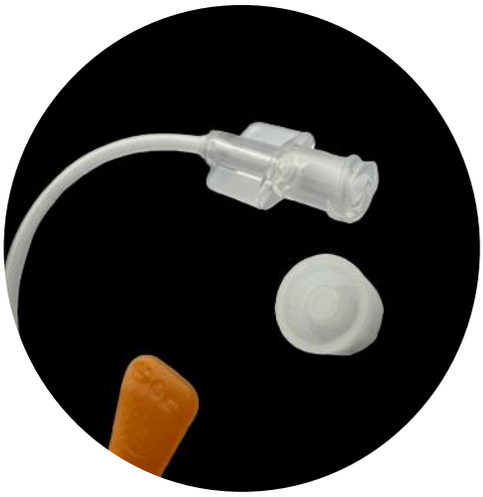
Microperfuseur a ailette et tubulure 7cm

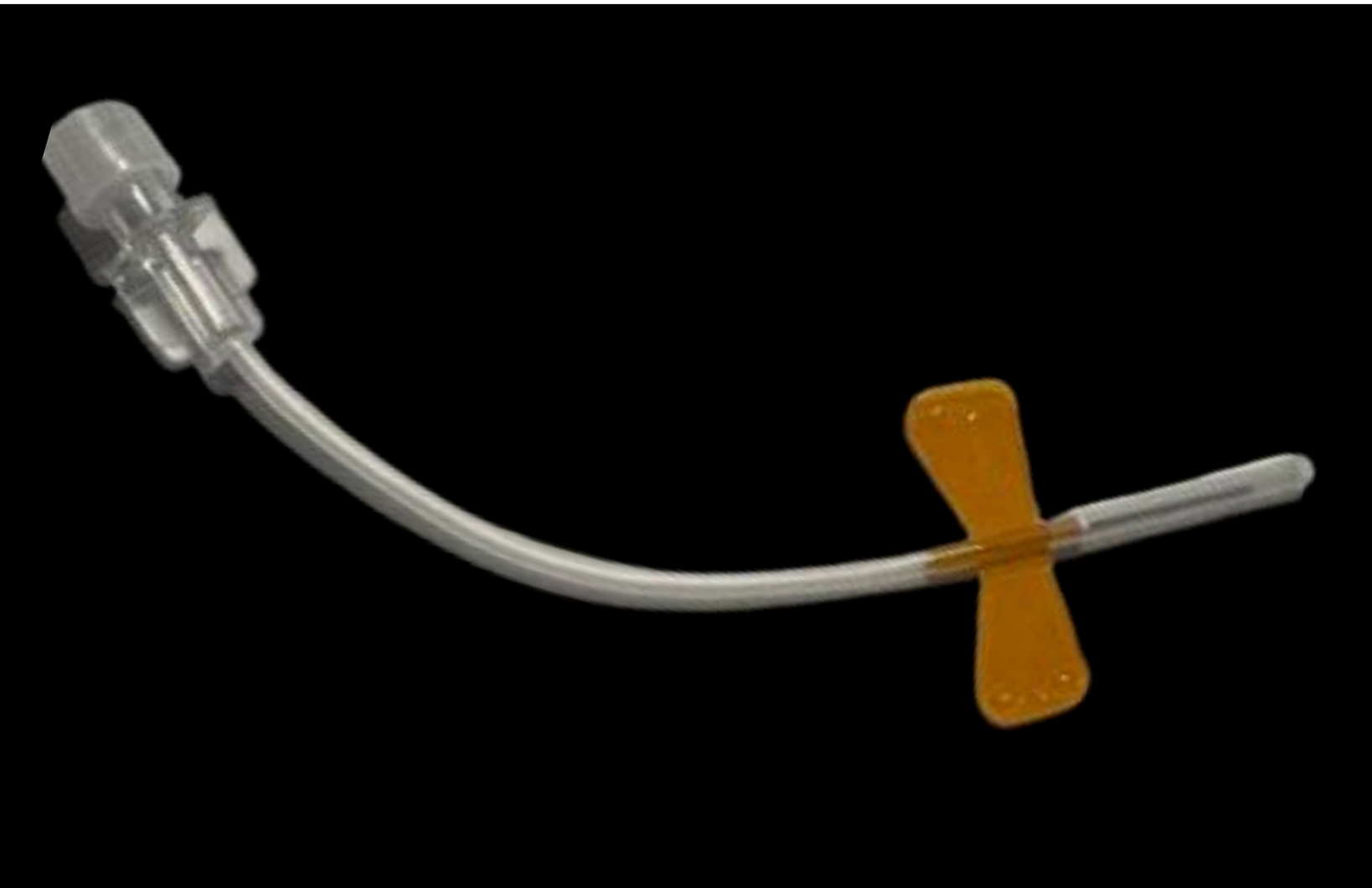
Description :

Microperfuseur à ailettes pour injection intermittente. Stérile, à usage unique, avec tubulure de 7cm, prémontée à un adaptateur Luer Lock

Caractéristiques:

- Tubulure de 7cm (70mm)
- Embout Luer lock
- Bouchon protecteur embout
- Existe en taille 19G à 27G





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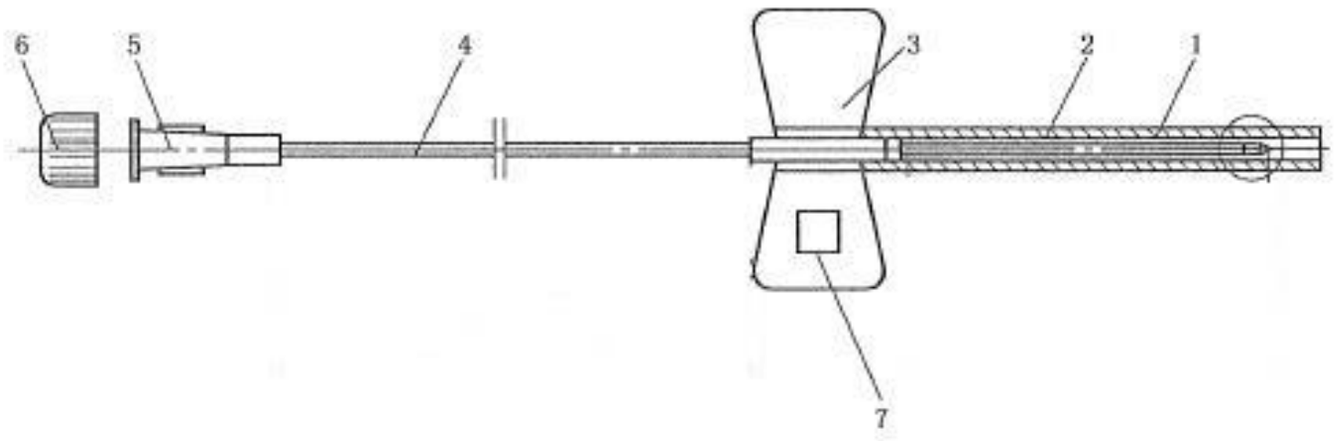
Caractéristiques Generales



Materiaux	1. Capuchon aiguille I.V	Polyethylène (PE)
	2. Aiguille I.V	Acier inoxydable grade 304
	3. Ailettes	ABS & PVC (sans DEHP)
	4. Tubulure	PVC (sans DEHP)
	5. Embout luer lock	ABS & PVC (sans DEHP)
	6. Bouchon de protection	PVC (sans DEHP) Polyethylène (PE)
	7. Inscription Gauge Aiguille sur ailette	N/A
	8. Lubrifiant	Polydimethyl siloxane
Pays d'origine	Chine	
Rep. Europeen	Caretechion GmbH	
Marquage CE	Dispositif Médical – Classe IIa selon MDR 745/2017 Annex IX Certificat de conformité de marquage CE n° DZ 2049691-1 délivré par le TUV RHEINLAND, n° d'organisme 0197. Code EMDN: A010102	EU-MDR 2017/745 CE 0197
Stérilité	10-6 SAL (SAL = Sterility Assurance Level = Niveau d'Assurance de Stérilité) Procédé de stérilisation : oxyde d'éthylène conforme à la norme internationale EN ISO 11135.	
Conservation	Durée de vie du produit (dans l'emballage d'origine) : 5 ans Température: Tenir à l'abri des rayons solaires	

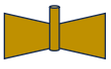
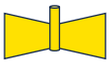
Produit Apyrogène: Oui
Présence de Latex : Non
Présence de DNR (caoutchouc naturel sec) :Non
Présence de Phtalates :Non
Présence de produits d'origine animale :Non

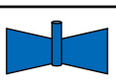
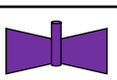
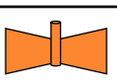
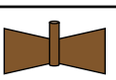
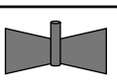
Importé & Distribué par: Metze SAS
10 rue de Penthièvre, 75008 Paris
commandes@metzecare.com

Fiche technique

Metze care

Caractéristiques spécifiques

Références Metze	JM1970MP	JM2070MP	JM2170MP	JM2270MP
Dimensions aiguille (Ø externe x Longueur)	19G x 3/4" (0.9mm x 19mm)	20G x 3/4" (0.9mm x 19mm)	21G x 3/4" (0.8mm x 19mm)	22G x 3/4" (0.7mm x 19mm)
Longueur Tubulure	70mm			
Volume mort	0.22ml			
Embout Luer lock male	Avec			
Bouchon protecteur embout	Avec			
Couleur Ailettes				

Références Metze	JM2370MP	JM2470MP	JM2570MP	JM2670MP	JM2770MP
Dimensions aiguille (Ø externe x Longueur)	23G x 3/4" (0.6mm x 19mm)	24G x 3/4" (0.55mm x 19mm)	25G x 3/4" (0.5mm x 19mm)	26G x 3/4" (0.45mm x 19mm)	27G x 3/4" (0.4mm x 19mm)
Longueur Tubulure	70mm				
Volume mort	0.22ml				
Embout Luer lock male	Avec				
Bouchon protecteur embout	Avec				
Couleur Ailettes					

Conditionnement et emballage

Conditionnement detaillé		
Emballage individuel	Boîte cartonnée 100 pcs	Master Carton 30 boites (30*10pcs)
Pouch papier plastique 50*83mm	18x12x15cm	46.5x37.5*46cm 6.2 kgs

Normes appliquées (suite)

Les normes appliquées dans la conception, la fabrication, l'emballage et l'étiquetage des lignes de produits des unités de prélèvement sécurisées sont énumérées dans le tableau suivant.

Normes / Réglementation	Description
MDR (EU) 2017/745	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MEDDEV2.7.1 Rev 4	Clinical Evaluation : A guide for manufacturers and notified bodies under directive
EN ISO 20417-2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
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 ISO 14971: 2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 10993-1:2020	Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
ISO 10993-4:2017	Biological evaluation of medical devices — Part 4:Selection of tests for interactions with blood
ISO10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993- 7:2008/AC:2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
ISO10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
EN ISO 10993-12 : 2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN 62366-1 : 2015	Medical devices — Part 1: Application of usability engineering to medical devices
ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-2:2015	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11138-1:2017	Sterilization of health care products - Biological indicators - General requirements
ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
ISO 13485:2016	Medical Devices – Quality management system – Requirements for regulatory purposes

Normes appliquées (suite et fin)

Les normes appliquées dans la conception, la fabrication, l'emballage et l'étiquetage des lignes de produits des unités de prélèvement sécurisées sont énumérées dans le tableau suivant.

Normes / Réglementation	Description
EN 17141:2020	Cleanrooms and associated controlled environments -Biocontamination control
ISO 14644-1:2015	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
ISO 14644-2:2015	Cleanrooms and Associated Controlled Environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ASTM D4169-16:2019	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F756-13:2013	Standard Practice for Assessment of Hemolytic Properties of Materials
EN ISO 8536-4:2020	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed(ISO 8536-4:2019)
EN ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
EN ISO 8536-14:2018	Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
ASTM F1980:2016	Standard guide for accelerated aging of sterile barrier systems for medical device
EN ISO 8536-4:2020	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed(ISO 8536-4:2019)
EN ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
EN ISO 8536-14:2018	Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
ASTM F1980:2016	Standard guide for accelerated aging of sterile barrier systems for medical device
EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
EN ISO 7153-1:2016	Surgical instruments – Metallic Materials -- Part 1: Stainless steel
EN ISO 6009:2016	Hypodermic needles for single use -- Colour coding for identification
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
EN ISO 7864:2016	Sterile hypodermic needles for single use --Requirements and test methods
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