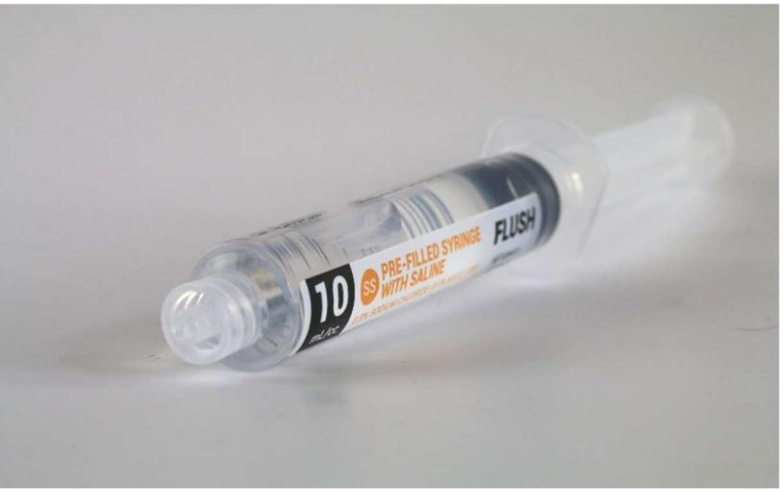
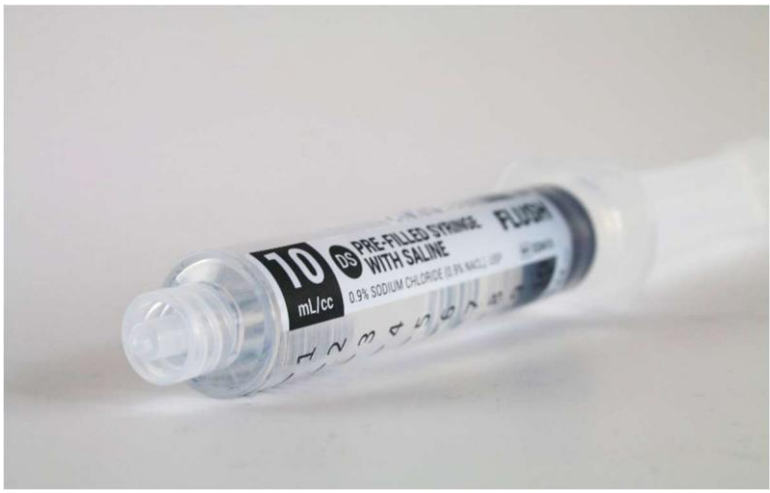
DISPENSYR™

FLUSH pre-filled syringes 0.9% NaCl





Product Description

The DispenSyr™ FLUSH pre-filled syringes with 0.9% NaCl provide additional safety and time savings when flushing IV access points, reducing the risk of CRBSI (catheter-related infections) and needle stick injuries. The number of required manual actions is significantly lowered, because the syringes are immediately deployable.

The syringes have a universal luer lock connection, which makes them suitable for use on all common IV access points.

The DispenSyr™ FLUSH syringes are available in two different versions: Single Sterile (SS) and Double Sterile (DS). The SS version has only a sterile fluid path, the DS version is also externally sterile and can therefore also be used in a sterile field and/or with immuno-compromised patients.

The versions are clearly distinguished by the following differences:

- Indication 'SS' or 'DS' on every packaging layer;
- Orange color code for SS, black color code for DS;
- Explanatory and warning text on every packaging layer and in the IFU;
- The SS version is wrapped in a transparent ribbon pack , the DS version is wrapped in a half-transparent, half-paper blister.

Both the SS and DS versions are available in three volumes: 3, 5, and 10 ml.

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Product specifications	
Intended use	Rinsing ('flushing') of IV access points to maintain patency
Classification	Medical Device class IIa
GMDN code	64786
Certification	• Produced in accordance with ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015 • CE certified in accordance with MDR EU 2017/745 (EU Declaration of Conformity & CE Certificate)
Notified Body	TUV Rhineland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany
European representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80 20537 Hamburg, Germany
Brand name	DispenSyr ™
Brand owner	Husk Medical B.V., Kelvinring 44, 2952 BG, Alblasserdam, The Netherlands
Importer & distributor	Husk Medical B.V., Kelvinring 44, 2952 BG, Alblasserdam, The Netherlands
Main materials	Liquid: 0.9% NaCl (USP) Barrel and plunger: PP (Polypropylene) Tip cap: PP + dye Stopper: elastomer Lubricant: silicone oil
Sterility	Radiation
Total shelf life	36 months
Storage conditions	Store between 15-25 degrees Celsius in a dry environment and keep out of direct sunlight.
Other specifications	• Latex free • PVC free • Pyrogen free • Single use
Packaging information	Individually sterile packed, and subsequently per 30 pieces in a shelf box.

DISPENSYR™

Applicable standards

Standard code	Description of standard
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223- 1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 14971:2019/A11:2021	Medical devices – Application or risk management to medical devices (ISO 14971:2019)
EN ISO 11737- 1:2018	Sterilization of medical devices - Microbiological methods – Part 1: 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
EN ISO 10993- 12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993- 12:2021)
EN ISO 10993- 23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN 556-1-2001+AC- 2006	Sterilization of medical devices. Requirements for medical devices to be designated sterile. Part 1. Requirements for terminally sterilized medical devices
EN ISO 10993- 1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993- 5:2009	Biological evaluation of medical devices - Part 5: Tests for in-vitro cytotoxicity
EN ISO 10993- 11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993- 18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 11607- 1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607- 2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
EN ISO 17141 :2020	Cleanrooms and associated controlled environments – Biocontamination control
EN ISO 7886- 1:2017	Sterile hypodermic syringes for single use Part 1: Syringes for manual use
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 11137- 1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137- 2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1

EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 20417:2021	Medical devices - Information supplied by the manufacturer
ISO 14644- 1:2015	Cleanrooms and associated controlled environments - Part 1 : Classification of air cleanliness by particle concentration
ISO 14644-2 :2015	Cleanrooms and associated controlled environments - Part 2 : Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISTA 3A	Packaged-Products For Parcel Delivery System Shipment 70 Kg (150 Lb) or Less
ASTM D 4169- 22	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1980:21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 10993- 10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization

Order details

Product code	Volume	Version	Individual packing	Packaging unit
520410	3 ml	SS	Transparent ribbon	BOX/30
520411	5 ml	SS	Transparent ribbon	BOX/30
520412	10 ml	SS	Transparent ribbon	BOX/30
520413	3 ml	DS	Semi-transparent blister	BOX/30
520414	5 ml	DS	Semi-transparent blister	BOX/30
520415	10 ml	DS	Semi-transparent blister	BOX/30