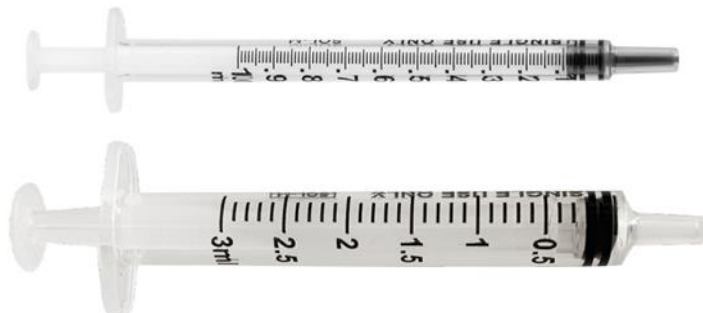


Technical Data Sheet



Product specification

| | |
|-----------------------------------|--|
| 1. Product name | Sol-M™ Slip Tip Syringe without Needle Sol-M™ Eccentric Tip Syringe without Needle |
| 2. Description | Sol-M™ Slip Tip / Eccentric Tip Syringe without Needle is a sterile, single-use, standard 3-piece hypodermic syringe. |
| 3. Indication for use | The Standard Slip Tip / Eccentric Tip Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body. |
| 4. Intended use | Sol-M™ Slip Tip / Eccentric Tip Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body. |
| 5. Intended users | Licensed healthcare professionals |
| 6. Instructions for Use | N/A |
| 7. Warning and precautions | Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury. |
| 8. Storage information | Keep dry, Keep away from sunlight, Storage condition: Temperature: 0°C~ 40°C, Humidity: ≤80% |

| | | |
|---------------------------------|------------|--|
| 9. Sizes and REF numbers | REF | Product Description |
| | 180011 | SOL-M 1ml Slip Tip Syringe w/o Needle |
| | P180011 | SOL-M 1ml Slip Tip Syringe w/o Needle |
| | 180011LDS | SOL-M 1ml Slip Tip Syringe w/o needle (low dead space) |
| | P180011LDS | SOL-M 1ml Slip Tip Syringe w/o needle (low dead space) |

| | |
|-------------|--|
| LD18001ILDS | SOL-M 1ml Slip Tip Syringe w/o Needle (low dead space) |
| 180003ST | SOL-M 3ml Slip Tip Syringe w/o Needle |
| P180003ST | SOL-M 3ml Slip Tip Syringe w/o Needle |
| 180005ST | SOL-M 5ml Slip Tip Syringe w/o Needle |
| P180005ST | SOL-M 5ml Slip Tip Syringe w/o Needle |
| 180010ST | SOL-M 10ml Slip Tip Syringe w/o Needle |
| P180010ST | SOL-M 10ml Slip Tip Syringe w/o Needle |
| 180010ET | SOL-M 10ml Eccentric Tip Syringe w/o Needle |
| P180010ET | SOL-M 10ml Eccentric Tip Syringe w/o Needle |
| 180020ST | SOL-M 20ml Slip Tip Syringe w/o Needle |
| P180020ST | SOL-M 20ml Slip Tip Syringe w/o Needle |
| P180050ST | SOL-M 50ml Slip Tip Syringe w/o Needle |
| 180020ET | SOL-M 20ml Eccentric Tip Syringe w/o Needle |
| P180020ET | SOL-M 20ml Eccentric Tip Syringe w/o Needle |
| 180060ET | SOL-M 60ml Eccentric Tip Syringe w/o Needle |
| P180060ET | SOL-M 60ml Eccentric Tip Syringe w/o Needle |

Sol-M™ 1ml Slip Tip Syringe in Low Dead Space Version

1. Description

Sol-M™ 1ml Slip Tip Syringe without Needle (in low dead space version) is designed with ultra-long tip gasket, featuring much less medication residual. The average measured waste space value ranges from 0.005ml to 0.011ml.

2. REF & Dead Space Volume

| REF | Description | Average (ml) | Minimum (ml) | Maximum (ml) |
|-------------|--|--------------|--------------|--------------|
| 18001ILDS | SOL-M 1ml Slip Tip Syringe w/o needle (low dead space) | 0.005 | 0.002 | 0.009 |
| P18001ILDS | SOL-M 1ml Slip Tip Syringe w/o needle (low dead space) | 0.005 | 0.002 | 0.009 |
| LD18001ILDS | SOL-M 1ml Slip Tip Syringe w/o Needle (low dead space) | 0.011 | 0.009 | 0.013 |

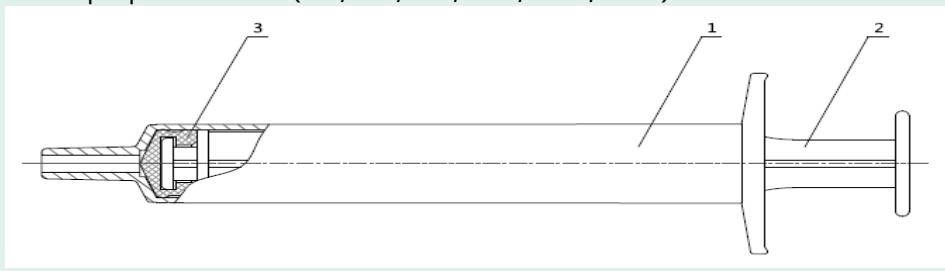
Technical information

| | | | | |
|-----------------------------------|--|------------------------------------|------------------------------------|---------------|
| 1. List of materials | Component name | Material | | |
| | Plunger | Polypropylene (PP) | | |
| | Barrel | Polypropylene (PP) | | |
| | Gasket | Latex Free Rubber | | |
| | Barrel Lubricant | Silicone oil | | |
| 2. Latex free | Yes | | | |
| 3. PHT / DEHP / BPA free | Yes | | | |
| 4. Materials of concern | <p>Not contain substances in a concentration that is above 0.1% w/w referred to following:</p> <ul style="list-style-type: none"> Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament Endocrine-disrupting substances identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (SVHC) or once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council in accordance with the criteria that are relevant to human health amongst the criteria established therein. | | | |
| 5. Shelf life | 5 years | | | |
| 6. Sterilization method | Sterilized with Ethylene Oxide | | | |
| 7. Packaging specification | 6.1 Sales unit | 18001I, P18001I | 100 units | Units per box |
| | | 18001ILDS, P18001ILDS, LD18001ILDS | 100 units | |
| | | 180003ST, P180003ST | 100 units | |
| | | 180005ST, P180005ST | 100 units | |
| | | 180010ST, P180010ST | 100 units | |
| | | 180010ET, P180010ET | 100 units | |
| | | 180020ST, P180020ST | 100 units | |
| | | 180020ET, P180020ET | 100 units | |
| | | 180060ET | 40 units | |
| | | P180060ET, P180050ST | 30 units | |
| | 18001I, 18001ILDS | 3200 units (32 boxes) | Units per case (Boxes per case) | |
| | P18001I, P18001ILDS | 800 units (8 boxes) | | |
| | LD18001ILDS | 800 units (8 boxes) | | |
| | 180003ST | 2700 units (27 boxes) | | |
| | P180003ST, P180005ST | 800 units (8 boxes) | | |

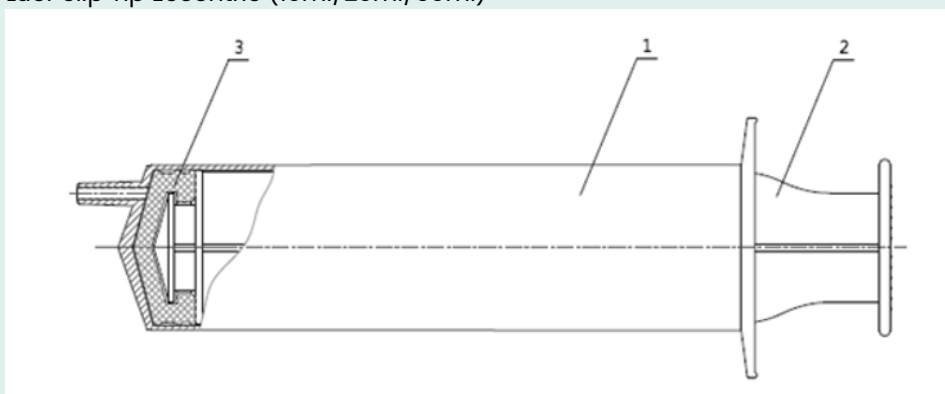
| | | |
|--|----------------------|-----------------------|
| | 180005ST | 1800 units (18 boxes) |
| | 180010ST, 180010ET | 1200 units (12 boxes) |
| | P180010ST, P180010ET | 1200 units (12 boxes) |
| | 180020ST, 180020ET | 800 units (8 boxes) |
| | P180020ST, P180020ET | 800 units (8 boxes) |
| | 180060ET | 320 units (8 boxes) |
| | P180050ST, P180060ET | 240 units (8 boxes) |

8. Technical Drawing

Luer Slip Tip Concentric (1ml/3ml/5ml/10ml/20ml/50ml)



Luer Slip Tip Eccentric (10ml/20ml/60ml)



1. Barrel 2. Plunger 3. Gasket

Quality and Regulatory information

| | | |
|----------------------------------|---|---|
| 1. Quality certificate | Quality Management System according to ISO 13485:2016 | |
| 2. Product classification | USA: Class II EU: Class Is+m according to Annex IX of EU MDR 2017/745 (CE2797) | |
| 3. List of standards | The product is compliant with the following standards and regulations: | |
| | Document reference | Title |
| | EN ISO 13485:2016, EN ISO 13485:2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes |

| | |
|---|---|
| EN ISO 15223-1:2021 | Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements |
| EN ISO 11135:2014, EN ISO 11135:2014/A1:2019 | Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices |
| EN ISO 11737-1:2018, EN ISO 11737- 1:2018/A1:2021 | Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products |
| EN ISO 11737-2:2020 | Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |
| EN ISO 14971:2019, EN ISO 14971:2019/A1:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 10993-1:2018 | Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process |
| EN ISO 10993-12:2021 | Biological evaluation of medical devices – Part 12: Sample preparation and reference materials |
| EN ISO 10993-7 :2008/AC:2009 | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals |
| EN ISO 10993-4:2017 | Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood |
| EN ISO10993-5:2009 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity |
| EN ISO 10993-10:2021 | Biological evaluation of medical devices – Part 10: Tests for skin sensitization |
| EN ISO 10993-11:2018 | Biological evaluation of medical devices – Part 11: Tests for systemic toxicity |
| EN ISO 10993-23:2021 | Biological evaluation of medical devices – Part 23: Tests for irritation |
| EN ISO 7886-1:2018 | Sterile hypodermic syringes for single use – Part 1: Syringes for manual use |
| 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 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 80369-20:2015 | Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods |

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Main Office: Sol-Millennium Medical Inc., 311 S. Wacker, Suite 4100, Chicago, IL 60606, USA.

www.solm.com

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| REV | 01 | Date | 2022.12.10 |
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