

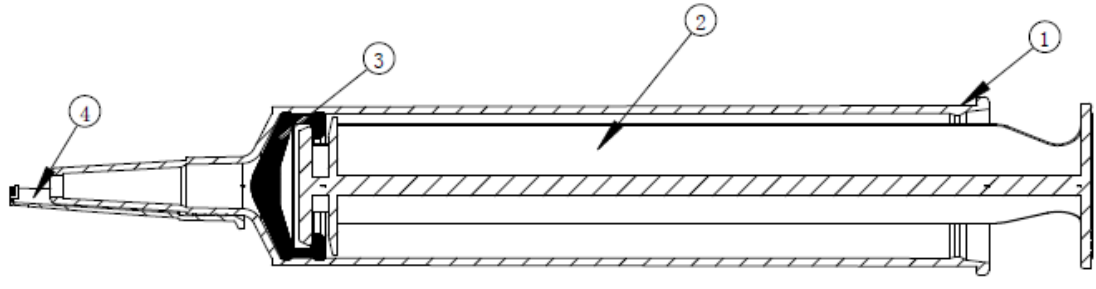
Technical Data Sheet

Product specification

| 1. Product name | SOL-M™ Catheter Tip Syringe without Needle | | | | |
|--------------------------|--|-----|------|----------|------|
| 2. Description | SOL-M™ Catheter Tip Syringe without Needle is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound. | | | | |
| 3. Characteristics | SOL-M™ Catheter Tip Syringe without Needle is sterilized by Ethylene Oxide Gas. Each Blister Pack, Dispenser Box and Case are labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements. | | | | |
| 4. Intended use | SOL-M™ Catheter Tip Syringe without Needle is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound. | | | | |
| 5. Instructions for use | N/A | | | | |
| 6. Sizes and REF numbers | <table border="1"><thead><tr><th>REF</th><th>Size</th></tr></thead><tbody><tr><td>180060CT</td><td>60ml</td></tr></tbody></table> | REF | Size | 180060CT | 60ml |
| REF | Size | | | | |
| 180060CT | 60ml | | | | |

SOL-MILLENNIUM®

Technical information

| | | | |
|--------------------------------|---|------------------------------|----------------|
| 1. List of Materials | Component name | Material | |
| | Plunger | PP: 5250T | |
| | Cap | PP: 5250T | |
| | Barrel | PP: 5250T | |
| | Gasket | Latex free rubber | |
| | Barrel Lubricant | Silicon oil: DC 360 12500cst | |
| 2. Latex free | YES | | |
| 3. PHT / DEHP / PVC / BPA free | YES | | |
| 4. Shelf life | 5 years | | |
| 5. Sterilization method | Sterilized using Ethylene Oxide | | |
| 6. Packaging specification | 6.1 Sales unit | 30 | Units per box |
| | | 240 | Units per case |
| 7. Technical Drawing |  <p>1. Barrel 2. Plunger 3. Gasket 4. Cap</p> | | |

Quality and Regulatory information

| 1. Quality certificate | Quality Management System according ISO 13485 | |
|---------------------------|---|--|
| 2. Product classification | Class Is+m according to Annex IX of MDD 93/42/EEC | |
| 3. List of standards | The product is compliant with the following standards and regulations: | |
| | Document reference | Title |
| | ISO 7886-1:1993/Cor 1:1995 | Sterile hypodermic syringes for single use-Part 1: Syringes for manual use |
| | ISO 10993-1:2009/Cor 1:2010 | Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process |
| | ISO10993-4:2002/Amd 1:2006 | 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 |
| | ISO10993-7:2008/Cor 1:2009 | Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals |
| | ISO10993-10:2010 | Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization |
| | ISO 15223-1:2016 | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| | ISO 11607-1:2006/Amd 1:2014 | Packaging for terminally sterilized medical devices—Part 1 |
| | ISO 11607-2:2006/Amd 1:2014 | Packaging for terminally sterilized medical devices—Part 2 |
| | ISO 11737-2:2009 | Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the validation of a sterilization process |
| | EN 980:2008 | Symbols for use in the labelling of medical devices |
| EN1041:2008+A1:2013 | Information supplied by the manufacturer of medical devices | |

REV

02

Date

04.01.2017