

# STERILE HYPODERMIC SYRINGE WITH NEEDLE FOR SINGLE USE Luer/Luer Lock


**1**
**USAGE FEATURES\***
**Intended Use:**

The Sterile Hypodermic Syringe for Single use is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

\*: Product features may vary depending on the intended use and usage of the product.

|            |                          |   |
|------------|--------------------------|---|
| <b>1.1</b> | Recommended usage period | Transient   |
| <b>1.2</b> | Usage                    | <input checked="" type="checkbox"/> Invasive<br><input type="checkbox"/> Non invasive                                 |
| <b>1.3</b> | Ergonomical features     | Perfect sealing.<br>Easy and regular sliding of the plunger.<br>No air leakage through gasket and end piece.          |
| <b>1.4</b> | Patient and user safety  | The product is for single use only and required warnings about the reuse of the product is prepared as an insert IFU. |

## 2 PRODUCT RANGE

|             |                                   |   |            |              |            |            |             |             |             |
|-------------|-----------------------------------|---|------------|--------------|------------|------------|-------------|-------------|-------------|
| <b>2.1</b>  | Volume                            |   | <b>2ml</b> | <b>2,5ml</b> | <b>3ml</b> | <b>5ml</b> | <b>10ml</b> | <b>20ml</b> | <b>50ml</b> |
| <b>2.2</b>  | Barrel Marking Specs              |   | 0.1ml      | 0.1ml        | 0.1ml      | 0.2ml      | 0.5ml       | 1ml         | 1ml         |
| <b>2.3</b>  | Dead Space Volume                 |   | < 0.07ml   | <0.075ml     | <0.075ml   | <0.075ml   | <0.10ml     | <0.15ml     | <0.20ml     |
| <b>2.4</b>  | Nozzle/Tip Type and Configuration | Luer, 2P Barrel, plunger  | ✓          | ✓            | -          | ✓          | ✓           | ✓           | -           |
|             |                                   | Luer, 3P Plunger, Barrel, Piston(gasket)  | ✓          | ✓            | ✓          | ✓          | ✓           | ✓           | ✓           |
|             |                                   | Luer Lock, 3P Plunger, Barrel, Piston(gasket)   | ✓          | ✓            | ✓          | ✓          | ✓           | ✓           | ✓           |
| <b>2.5</b>  | Barrel Transparency               | Transparent   | ✓          | ✓            | ✓          | ✓          | ✓           | ✓           | ✓           |
|             |                                   | UV Resistant  | ✓          | ✓            | ✓          | ✓          | ✓           | ✓           | ✓           |
|             |                                   | Opaque  | -          | -            | -          | -          | -           | -           | ✓           |
| <b>2.6</b>  | Length (mm)                       |   | 64.05      | 64.05        | 70.20      | 74.40      | 84.80       | 98.00       | 182         |
| <b>2.7</b>  | Diameter (mm)                     |   | 10.09      | 10.09        | 11.20      | 13.65      | 17.94       | 21.62       | 31.6        |
| <b>2.8</b>  | Nozzle Type                       | Luer, Luer lock, % 6 conical, 1.2mm   |            |              |            |            |             |             |             |
| <b>2.9</b>  | Hypodermic Needle                 | Needle configurations are in the table below  |            |              |            |            |             |             |             |
| <b>2.10</b> | Operation Mode                    | The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient. |            |              |            |            |             |             |             |
| <b>2.11</b> | Graduation Legibility             | Legible   |            |              |            |            |             |             |             |

Hypodermic needle product range table

| <b>2.12</b> | Sizes                                      | 14G   | 15G    | 16G    | 18G    | 19G    | 20G    | 21G    | 22G    | 23G  | 25G | 26G  | 27G    | 29G  | 30G  |
|-------------|--|---|--------|--------|--------|--------|--------|--------|--------|------|-----|------|--------|------|------|
|             | Needle lengths (*): with 15 microns filter | 1"  | 1 1/4" | 1"     | 1"     | 1 1/2" | 1 1/2" | 5/8"   | 1 1/4" | 1"   | 1"  | 1/2" | 1 1/2" | 1/2" | 1/2" |
|             |  |   |        | 1"(*)  | 1"(*)  |        |        | 1 1/2" | 1 1/2" |      |     |      |        |      |      |
|             |  | 1 1/2"  | 1 1/2" | 1 1/4" | 1 1/2" | 1 1/4" | 2"     |        |        | 1/3" |     |      |        |      |      |
|             |  |   |        | 1 1/2" | 1 1/2" |        |        |        |        |      |     |      |        |      |      |
| <b>2.13</b> | Needle Cap Color                           | Transparent and colorless                                   |        |        |        |        |        |        |        |      |     |      |        |      |      |
| <b>2.14</b> | Needle Hub Color                           | Transparent and with above colors                           |        |        |        |        |        |        |        |      |     |      |        |      |      |
| <b>2.15</b> | Needle Tip Configuraiton                   | Back bevel needle   |        |        |        |        |        |        |        |      |     |      |        |      |      |
| <b>2.16</b> | Configuration                              | Protective cap, needle, silicone oil, adhesives, needle hub |        |        |        |        |        |        |        |      |     |      |        |      |      |

2P: 2 Parça, 3P: 3 Parça

**3 PRODUCT COMPONENTS**

|     |                                   |   |                       |
|-----|-----------------------------------|---|-----------------------|
| 3.1 | Barrel Material                   | PP – Polypropylene  |                       |
| 3.2 | Plunger Material                  | PE – Polyethylene<br>PP - Polypropylene                                       |                       |
| 3.3 | Plunger Stopper (Gasket) Material | Isoprene rubber, Latex free   |                       |
| 3.4 | Lubricant Composition             | Silicone oil  |                       |
| 3.5 | Protective Cap Material           | PP - Polypropylene  |                       |
| 3.6 | Adhesive Material                 | Epoxy Resin   |                       |
| 3.7 | Needle and Needle Hub Material    | Needle  | SS304 Stainless Steel |
|     |                                   | Needle Hub  | PP – Polypropylene    |
| 3.8 | Packing Material                  | Medical grade paper and transparent film for EO (individually blister packed) |                       |

**4 REGULATORY INFORMATION**

|     |                       |   |  |
|-----|-----------------------|---|--|
| 4.1 | Related Directive     | 93/42/EEC Medical Devices Directive, FDA 21 CFR part 820                    |  |
| 4.2 | Risk Sınıfı ve Kuralı | IIa, Rule 6   |  |
| 4.3 | Ürün Standardı        | ISO 6009<br>ISO 7864<br>ISO 7886-1<br>ISO 7886-2<br>ISO 80369-7<br>ISO 9626 |  |
| 4.4 | GMDN Kodu             | 35904 Syringe, hypodermic, metered-delivery.                                |  |

**5 STERILIZATION AND SHELF LIFE**

|     |                      |               |
|-----|----------------------|---------------|
| 5.1 | Sterilization Method | EO sterilized |
| 5.2 | Shelf Life           | 5 years       |

**6 STORAGE / TRANSPORTATION CONDITIONS**

20-80 %RH, 0-45°C  
 Protect from direct sunlight.  
 Should be protected from impacts during transportation.