

## Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer lock



### 1 USAGE FEATURES\*

Intended Use:

The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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

|     |                          |                                                                                                                                                                                                                                                                               |
|-----|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1 | Recommended usage period | Transient                                                                                                                                                                                                                                                                     |
| 1.2 | Usage                    | <input checked="" type="checkbox"/> Invasive<br><input type="checkbox"/> Non invasive                                                                                                                                                                                         |
| 1.3 | Ergonomical features     | Double ring contact point on the gasket to provide perfect sealing<br>Easy and regular sliding of the plunger<br>No air leakage through gasket and end piece<br>Integrated plunger stopper ring at the bottom of the barrel to prevent unintended pull out of the plunger rod |
| 1.4 | Patient and user safety  | The product is a single use product and required warnings about the reuse of the product is prepared as an insert IFU.                                                                                                                                                        |

## 2 PRODUCT RANGE

| Volume                | 2ml                                                                                                                                                                 |                 | 5 ml                    |                 | 10ml                    |                 | 20ml                    |                 |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-------------------------|-----------------|-------------------------|-----------------|-------------------------|-----------------|
| Barrel Marking Specs  | 0,1ml                                                                                                                                                               |                 | 0,2ml                   |                 | 0,5ml                   |                 | 1ml                     |                 |
| Tip type              | Luer, 6% conical                                                                                                                                                    |                 | Luer, 6% conical        |                 | Luer, 6% conical        |                 | Luer, 6% conical        |                 |
| Configuration         | Gasket, Plunger, Barrel                                                                                                                                             |                 | Gasket, Plunger, Barrel |                 | Gasket, Plunger, Barrel |                 | Gasket, Plunger, Barrel |                 |
| Barrel Transparency   | Transparent                                                                                                                                                         |                 | Transparent             |                 | Transparent             |                 | Transparent             |                 |
| Needle Size           | 23G 1"                                                                                                                                                              | 23G 1 ¼"        | 22G 1 ¼"                | 22G 1 ½"        | 21G 1 ½"                | 22G 1 ½"        | 20G 1 ½"                | 21G 1 ½"        |
| Reference Code        | 21IN-0203232502                                                                                                                                                     | 21IN-0203233201 | 21IN-0503223201         | 21IN-0503223801 | 21IN-1003213801         | 21IN-1003223801 | 21IN-2003203801         | 21IN-2003213801 |
| Syringe Length (mm)   | 87,1                                                                                                                                                                | 64,05           | 64,05                   | 70,20           | 74,40                   | 84,80           | 98,00                   | 182             |
| Syringe Diameter (mm) | 6,85                                                                                                                                                                | 10,09           | 10,09                   | 11,20           | 13,65                   | 17,94           | 21,62                   | 31,6            |
| 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. |                 |                         |                 |                         |                 |                         |                 |
| Graduation Legibility | Legible                                                                                                                                                             |                 |                         |                 |                         |                 |                         |                 |

## 3 PRODUCT COMPONENTS

|     |                         |                                                                           |
|-----|-------------------------|---------------------------------------------------------------------------|
| 3.1 | Piston(Gasket) Material | Isoprene rubber, Latex free                                               |
| 3.2 | Barrel Material         | PP – Polypropylene                                                        |
| 3.3 | Plunger Material        | PE – Polyethylene<br>PP – Polypropylene                                   |
| 3.4 | Lubricant Composition   | Silicone oil for three part syringe<br>Slip additive for two part syringe |

## 4 REGULATORY INFORMATION

|     |                     |                                                                           |
|-----|---------------------|---------------------------------------------------------------------------|
| 4.1 | Related Directive   | 93/42/EEC Medical Device Directive                                        |
| 4.2 | Risk Class and Rule | IIa, Rule 2                                                               |
| 4.3 | Product Standard    | ISO 7864<br>ISO 7886-1, ISO 7886-2<br>ISO 8537<br>ISO 9626<br>ISO 80369-7 |
| 4.4 | GMDN Code           | 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, 5-35°C  
Protect from direct sunlight.  
Should be protected from impacts during transportation.

## 7 HISTORY OF DOCUMENT REVISION

| Rev. Date  | Rev. No | Reason for Revision |
|------------|---------|---------------------|
| 03.01.2020 | 00      | First published.    |