



# IFP Medical

Engineered for Compliance and Consistency

## IFP Medical – Fixed Needle Syringe Kits

IFP Medical’s Fixed Needle Syringe Kits include essential components for safe, accurate, and hygienic medication administration. Each kit contains Sol-Millennium® fixed needle syringes (also known as insulin syringes) and 70% isopropyl alcohol swabs to support proper skin preparation and injection technique. Designed for convenience and compliance, these kits help improve dosing accuracy while reducing the risk of contamination and needlestick injuries.



Complete Sterile Injection Solutions You Can Trust





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## Applications

- GLP-1 receptor agonist administration (semaglutide, tirzepatide, liraglutide)
- Insulin injections for diabetes management
- Compounded injectable therapies in pharmacies (503A / 503B)
- Patient self-administration and home healthcare use
- Clinical and outpatient care settings
- Physician offices, clinics, and ambulatory care centers

## Key Features

- Includes Sol-Millennium® fixed needle syringes and alcohol swabs
- 70% isopropyl alcohol swab for skin preparation
- Individually wrapped components
- Tri-bevel needle for smooth injections
- Low dead space reduces medication waste
- Clear markings for accurate dosing
- Integrated safety features help prevent needlestick injuries
- No needle recapping required
- Convenient, ready-to-use kit

## Kit Components



Sol-Millennium® fixed needle syringes



Sterile Alcohol Swabs





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## Technical Information

### Material Construction

Component	Material
Needle cap	Polypropylene
Cannula	Stainless steel: SUS304
Gasket	Latex-free rubber
Barrel	Polypropylene
Plunger	Polypropylene
Protective cap	Polypropylene
Adhesive	UV glue
Needle Lubricant	Silicon oil
Barrel Lubricant	Silicon oil
Alcohol	Isopropyl alcohol – Concentration 70% Purified water – Concentration 30%

### Product Specifications

Specification	Details
Sterilization Method	<ul style="list-style-type: none"> <li>Sol-Millennium® fixed needle syringes: Ethylene Oxide Sterilization</li> <li>Alcohol Swabs: Gamma Irradiation</li> </ul>
Packaging	Items in the kit are all individually packaged and placed in 9" x 12" 2 Mil Bags. Wide range of kit quantities available.
Shelf Life	IFP Medical Fixed Needle Syringe Kits have a shelf life of 5 years from the date of sterilization.





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## Indication for use/Intended use:

The Insulin Standard Syringe with Fixed Needle is used to inject insulin into the body with the calibration units of U-100.

## Intended users

Licensed health care professional (HCP) or self-injecting patients after proper training obtained from HCP.

## Storage information

Keep dry, Keep away from sunlight, Store away from sources of heat or ignition, away from incompatible materials

Storage condition: Temperature: 0°C ~ 40°C, Humidity: ≤ 80%

## Warning and precautions

### Cautions:

- Single-use device. Re-use or use if the syringe is damaged or opened may lead to infection or other illness/ injury.
- Users must be trained by a healthcare professional and follow the Instructions For Use. Failure to follow these instructions could result in serious injury to the patient and/or clinician.
- Consult a healthcare provider about your medical condition and appropriate treatment. Always follow the medication manufacturer's instructions for use, contraindications, warnings, and precautions.
- Before changing to a shorter needle, consult with your healthcare professional.
- Sharp object. Risk of sharp injuries.





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## Quality and Compliance

<b>Quality certificate</b>	Quality Management System according to ISO 13485.	
<b>Product classification</b>	USA: Class II EU: Class IIa according to Annex IX of EU MDR 2017/745 (CE2797)	
<b>List of standards</b>	<b>The product is compliant with the following standards and regulations:</b>	
	<b>Document reference</b>	<b>Title</b>
	EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
	(EU) 2017/745 Medical Devices Regulation (MDR)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
	EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
	EN ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
	EN ISO 7864: 2016	Sterile hypodermic needles for single use – Requirements and test methods
	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	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
	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 -- Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/DAMd 1:2018)
	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 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	





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EN ISO 11607-1:2020 EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020 EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages
ISTA 3A 2018	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipment 70kg (150 lb) or Less
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
ASTM F2825-18	Standard Practice For Climatic Stressing Of Packaging Systems For Single Parcel Delivery
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 14971: 2019 EN ISO 14971:2019/A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008 EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants
EN ISO 10993-10:2023	Biological evaluation of medical devices — Part 10 : Tests for skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

### Toxicological Information

<b>Chronic Toxicity/Carcinogenicity</b>	This product is not expected to cause long term adverse health effects.
<b>Genotoxicity</b>	This product is not expected to cause any mutagenic effects.
<b>Reproductive/Developmental Toxicity</b>	This product is not expected to cause reproductive or developmental health effects





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## Ordering Guide



[1]	[2]	[3]
Syringe Configuration	Syringe Quantity Per Kit	Alcohol Swabs Quantity Per Kit
<ul style="list-style-type: none"> <li>• 19: 1ml – 31G – 15/64"</li> <li>• 18: 1ml – 31G – 5/16"</li> <li>• 17: 1ml – 30G – 5/16"</li> <li>• 16: 1ml – 30G – 1/2"</li> <li>• 15: 1ml – 29G – 1/2"</li> <li>• 14: 1ml – 28G – 1/2"</li> <li>• 13: 1ml – 27G – 5/8"</li> <li>• 12: 1ml – 27G – 1/2"</li> <li>• 11: 0.5ml – 31G – 5/16"</li> <li>• 10: 0.5ml – 31G – 15/64"</li> <li>• 09: 0.5ml – 30G – 5/16"</li> <li>• 08: 0.5ml – 30G – 1/2"</li> <li>• 07: 0.5ml – 29G – 1/2"</li> <li>• 06: 0.5ml – 28G – 1/2"</li> <li>• 05: 0.5ml – 27G – 1/2"</li> <li>• 04: 0.3ml – 31G – 5/16"</li> <li>• 03: 0.3ml – 31G – 15/64"</li> <li>• 02: 0.3ml – 30G – 5/16"</li> <li>• 01: 0.3ml – 30G – 1/2"</li> </ul>	<ul style="list-style-type: none"> <li>• 05: 5 Syringes Per Kit</li> <li>• 10: 10 Syringes Per Kit</li> <li>• 20: 20 Syringes Per Kit</li> </ul>	<ul style="list-style-type: none"> <li>• 005: 5 Alcohol Swabs</li> <li>• 010: 10 Alcohol Swabs</li> <li>• 020: 20 Alcohol Swabs</li> <li>• 030: 30 Alcohol Swabs</li> <li>• 040: 40 Alcohol Swabs</li> <li>• 050: 50 Alcohol Swabs</li> <li>• 060: 60 Alcohol Swabs</li> <li>• 070: 70 Alcohol Swabs</li> <li>• 080: 80 Alcohol Swabs</li> <li>• 090: 90 Alcohol Swabs</li> <li>• 100: 100 Alcohol Swabs</li> </ul>

**IFP1810020**

Fixed Needle Syringe Kit for Rx & Home Use, pre-packed in a zip-lock bag. Each kit includes 10 pcs of 1 mL sterile insulin syringe individually packed with fixed needle (31G, 5/16") and 20 pcs sterile alcohol pads.

Part Number

Description

\*Configurations not held in stock are available with a minimum order quantity (MOQ)

\*\*Additional configurations available upon request.

