

IntegriMedical®

NEEDLE FREE INJECTION SOLUTIONS

INSTRUCTIONS FOR USE

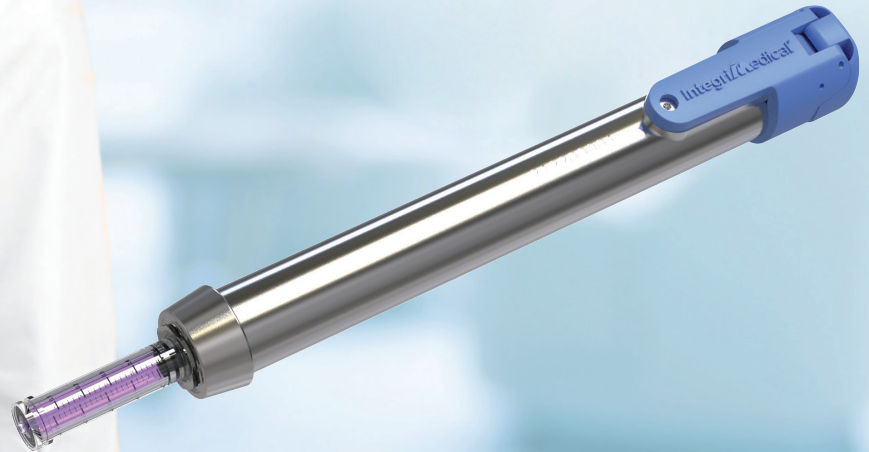


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For instructions in other languages, please download the relevant eIFU from <https://integrimedical.com/instructions-for-use>

INTENDED USE, INDICATIONS FOR USE, AND INTENDED USERS

The Needle Free Injection System (NFIS) is intended for Intramuscular (IM) or Subcutaneous (SC) injections to deliver upto 0.5ml of drugs and biologics. The NFIS is intended for home and professional use by trained healthcare professionals and by the patients authorized by their physicians to self inject. The NFIS is intended for paediatric and adult populations.

The NFIS is not intended to be used with thick high viscosity molecular drugs or chemically aggressive drugs.


SYSTEM CONTENTS

NFIS

2 x Pre-filled Syringe Adapter

10 x Cartridge

Injection Test Foam

 Please practice injecting into the foam until you are comfortable and proficient in using the device

2 x Vial Adapter

Loader

NFIS Device

Zipper Bag

SYSTEM CONTENTS

1. NFIS Device
(reusable).....



2. Loader
(reusable).....

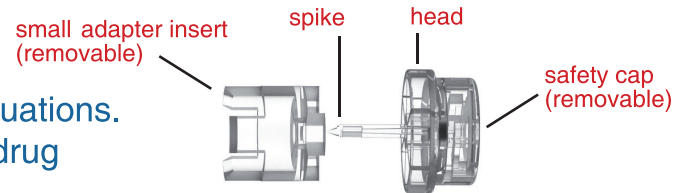


3. Cartridge (x10)
(single use).....



4. Vial Adapter (x2).....

Single use or multiple use for maximum 10 actuations.
Duration use to be as per WHO guideline are drug
manufacturer guidelines for open vials.



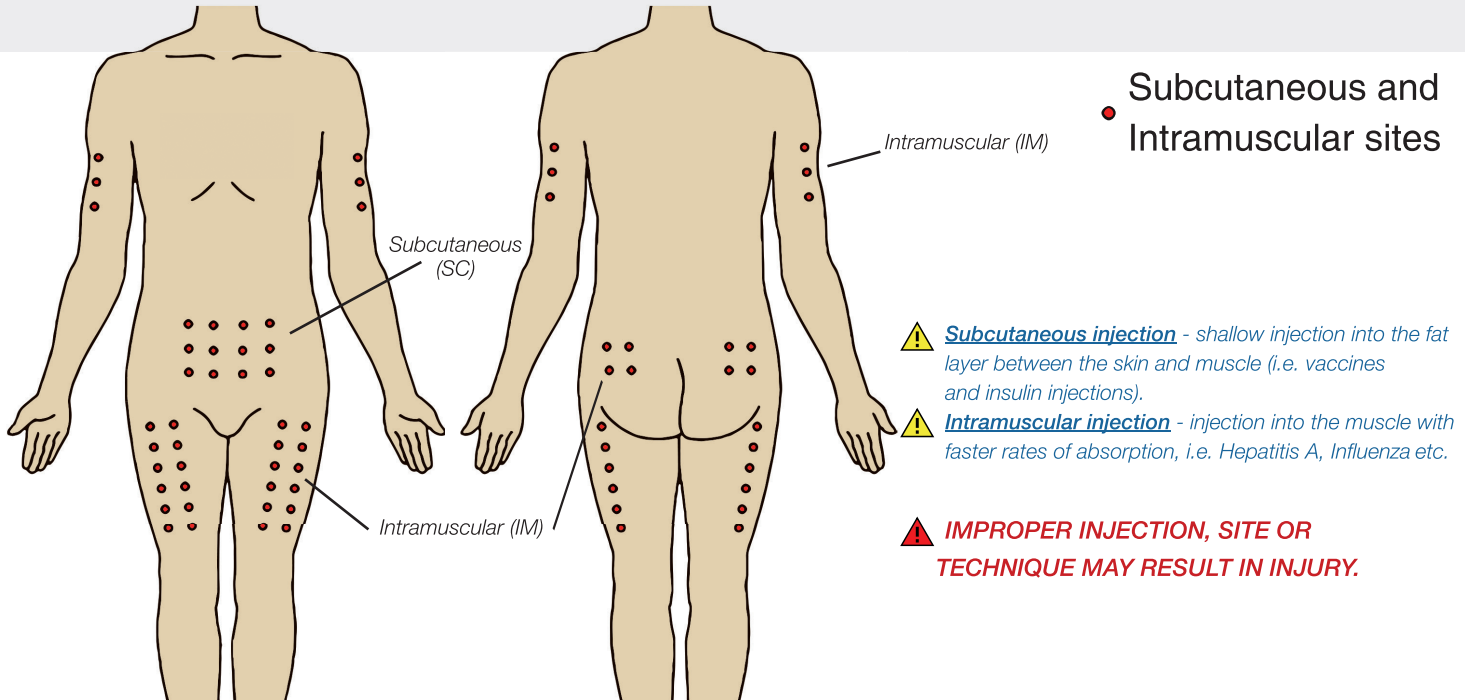
5. Pre-filled Syringe Adapter (x2)
(single use).....



INSTRUCTIONS FOR USE

STEP 1 - SELECTING AND PREPPING THE INJECTION SITE

1. Select a site with a low likelihood of infection, where the skin is intact and free from irritation, abrasions, bruises etc.



INSTRUCTIONS FOR USE

STEP 1 - SELECTING AND PREPPING THE INJECTION SITE - continued

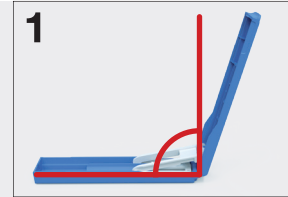
2. Gather & place all the supplies (NFIS Kit, medicine vial, adhesive bandage, alcohol wipes) on a clean, dry surface. Wash hands and wear sterile gloves.
3. Inspect ALL components and packaging for damage. DO NOT use any component which has been dropped or damaged. Replace damaged sterile component packages and components with NEW ones.
4. Clean the injection site and let it dry.
 - ⚠ *DO NOT TOUCH PREPPED INJECTION SITE UNTIL PERFORMING THE INJECTION.*
 - ⚠ *PLEASE READ AND FOLLOW INSTRUCTIONS RECOMMENDED BY THE DRUG / BIOLOGIC MANUFACTURE OF APPROPRIATE DOSAGE, STORAGE, INJECTION SITE, ALLERGIES ETC. FOR THEIR MEDICATION.*

INSTRUCTIONS FOR USE

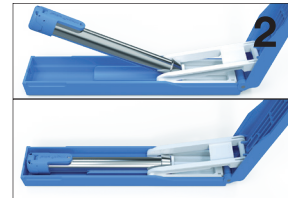
STEP 2 - PREPARING THE NFIS DEVICE

⚠ *Clean and disinfect the NFIS Device and Loader before each use according to the step 7 instructions in the Instructions for Use*

1. Open the Loader until fully extended.

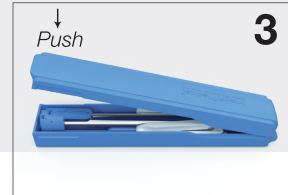


2. Slide NFIS Device's barrel into the Loader first at 30° angle, then set the NFIS Device securely in the groove inside.



3. Firmly push down the Loader's top lid at the indicated location to load the NFIS Device.

⚠ *The loader will spring back up to an open position when ready.*



4. Open the loader to full extension, lift the NFIS Device and remove from loader. Set aside.

⚠ *DO NOT dry fire* the NFIS Device; dry firing will damage the NFIS Device.*

⚠ *DO NOT drop the NFIS Device; dropping the NFIS Device may damage components such as the safety cap etc. or affect the functioning of the NFIS Device*

* dry firing - pressing the injection button without a Cartridge or with an empty Cartridge



INSTRUCTIONS FOR USE

STEP 3A - PREPARING THE VIAL ADAPTER

1. Remove the Vial Adapter from the package.

- ⚠ **DO NOT TOUCH THE SPIKE** - contamination may occur
- ⚠ If using a small vial (**13mm or smaller**), the Vial Adapter is ready to use.
- ⚠ If using a larger vial (**over 13mm**), DO NOT use the Small Adapter Insert; remove it from the Vial Adapter and discard it (see Pic. 1a).



2. Wipe the rubber top of the medicine vial with an alcohol wipe.



3. Insert the Vial Adapter's spike into the center of medicine vial.

- ⚠ Placing medicine vial on the flat surface may be helpful.



4. Twist counterclockwise to remove Safety Cap from the Vial Adapter.

- ⚠ If using a multidose vial, set the cap aside to recap & when the injection is completed. Preserve sterility.




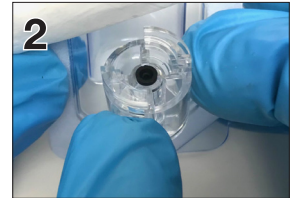
INSTRUCTIONS FOR USE

STEP 3B – PREPARING THE PRE-FILLED SYRINGE ADAPTER

1. Carefully remove the cap from the tip of pre-filled syringe. Ensure all air is removed from the pre-filled syringe prior to connecting it to the adapter.

2. Remove the pre-filled syringe adapter from the package.

 *Do not touch the tip of pre-filled syringe and prefilled syringe adapter – contamination may occur.*



3. Attach the pre-filled syringe adapter by twisting it onto the tip of the pre-filled syringe.



4. Twist the pre-filled syringe adapter and pre-filled syringe together until you hear a click.

INSTRUCTIONS FOR USE

STEP 4A – PREPARING THE CARTRIDGE WITH VIAL ADAPTER

1. Remove the Cartridge from packaging.



2. Place the Cartridge on the Vial Adapter. Turn clockwise until secure.



3. While holding the medicine vial and the Vial Adapter firmly in place, turn the medicine vial upside down and slowly pull back the plunger to the required dosage fill line.



⚠️ *If plunger inadvertently pulled completely outside the body of cartridge, the component may get contaminated. Please replace all system components with new components and replace the contaminated medicine vial. Restart the procedure at step 3B.1*

4. Place the medicine vial right side up. Hold the vial adapter and turn filled Cartridge counter clockwise to remove.

⚠️ *When planning on additional actuations with the multi-dose drug / biologic vials, put the Protective Cap back on the Vial Adapter and store according to drug / biologic labeling storage conditions or applicable WHO guidelines.*



INSTRUCTIONS FOR USE

STEP 4B – PREPARING THE CARTRIDGE WITH PRE-FILLED SYRINGE ADAPTER

1. Remove the Cartridge from packaging.



2. Place the Cartridge on the Pre-filled Syringe Adapter.
Hold the adapter and turn clockwise until secure.



3. While holding the medicine pre-filled syringe and the Pre-filled Syringe Adapter firmly in place, turn the medicine pre-filled syringe upside down. Slowly pull back the plunger of the NFIS cartridge, while pressing the plunger of Pre-filled Syringe. Ensure the entire drug is transferred into the cartridge.



⚠ *If plunger inadvertently pulled completely outside the body of cartridge, the component may get contaminated. Please replace all systems components with new components and replace the contaminated medicine pre-filled syringe. Restart the procedure at 4B.1*

4. Place the medicine pre-filled syringe right side up.
Turn filled cartridge counter clockwise to remove.



INSTRUCTIONS FOR USE

STEP 5 – PREPARING THE CARTRIDGE – continued

⚠ DO NOT TOUCH THE TIP OF THE CARTRIDGE.

1. Check for air bubbles.

⚠ *If air bubbles are present, use your finger to flick the side of the Cartridge to move the bubble to the top and gently pushing up on the plunger to remove air bubble.*



2. Insert filled Cartridge (plunger first) into the NFIS Device.



3. Turn Cartridge clockwise until secure.



SYSTEM IS NOW READY TO USE

INSTRUCTIONS FOR USE

STEP 6 – PERFORMING THE INJECTION

⚠ DO NOT POSITION THE CARTRIDGE DIRECTLY OVER A BLOOD VESSEL.

1. Ensure the Patient is comfortable in a relax position.
Position the NFIS Device at 90° angle to injection site.
For subcutaneous injection, pinch and pull up the skin over the injection site.

2. Use your thumb to lift open the Safety Cap on top of the NFIS Device.

3. Apply even pressure to ensures no gap between skin & cartridge.

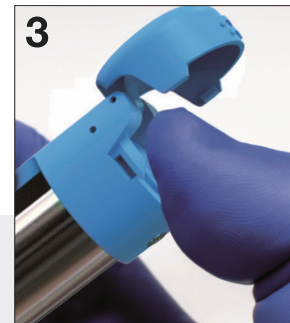
⚠ MAINTAIN THE PRESSURE TO AVOID INCOMPLETE INJECTION.

4. Firmly press the Trigger Button and hold the NFIS Device in place for few seconds after pressing the Trigger Button to allow for medication to penetrate the skin.

It is normal to have a drop of medication at the site due to some back flow

⚠ Please note you'll hear a click when injection starts.

5. Post complete delivery of medicine hold NFIS Device at injection site for 5 - 7 seconds.



INSTRUCTIONS FOR USE

STEP 6 – PERFORMING THE INJECTION – continued

6. Apply an Adhesive Bandage at the injection site after injection.
7. Twist cartridge counter-clockwise and remove from NFIS Device.

 *Discard Cartridge after every use according to appropriate disposal method.*




The use of this device may not extend the drug / biologic use-by date, if the medicine use by date expires while using the device replace the medicine vial with a new one.

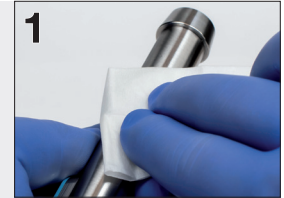
INSTRUCTIONS FOR USE

STEP 7 - AFTER PERFORMING AN INJECTION

1. NFIS Device & Loader: Disinfect with alcohol wipes & store in kitbox for next use.

 *Store the NFIS Device without the Cartridge attached in the kitbox.*


 *Do not expose to extreme temperatures.*



2. Cap and store Vial Adapter, if not empty & has not been actuated more than 10 times or store Vial Adapter as per instructions from drug manufacturer or as per relevant WHO guidelines. For next dose follow directions beginning on step 3. Discard empty medicine vial according to appropriate disposal method. Discard Vial Adapter according to your local requirement or WHO guidelines.

3. Discard empty Pre-filled Syringe Adapter according to appropriate disposal method.

4. Discard used Cartridge and other disposables according to the appropriate disposal method.

 *Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information and that the use of NFIS Device is not a substitute for a biological safety cabinet (BSC).*

5. For next dose refer to step 3.

CLINICAL NOTES

THE FOLLOWING LOCAL RESPONSES MAY OCCUR WITH NEEDLE FREE INJECTION SYSTEM.

- a) **Some medications may produce a burning, aching or stinging sensation. Check the medication labeling for a description of local reactions.**
- b) **Following the injection, a drop of blood or fluid may appear. Blood and/or fluid loss can be minimized by immediately pressing cotton ball or gauze at the injection site for a few seconds and thereafter apply adhesive bandage.**
- c) **To ensure delivery of dosage to Intramuscular (IM) & Subcutaneous (SC) target tissue, refer to Page 13 and for proper injection technique. Refer to drug / biologic product labeling for additional information.**
- d) **It is normal to have a drop of medication at the side due to some back flow.**

SYMBOL GLOSSARY



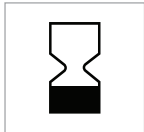
Manufacturer
Identifies the manufacturer of the medical device.



Authorized representative in the European Community
Indicates the authorized representative in the European Community.



Date of manufacturer
Indicates the date on which the medical device was manufactured.



Use by date
Indicates that the medical device should not be used after the accompanying date.



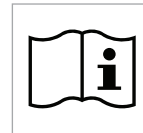
Quantity
Indicates number of unit per package.



Serial number
Identifies the manufacturer's serial number of the medical device.



Lot Number
Identifies the manufacturing lot number.



Operating instructions
The operating instructions should be consulted and followed when operating the medical device.



Catalogue number
Identifies the manufacturer's catalogue number to be used while placing the order



Caution
Caution is necessary when operating the medical device. Operator awareness is necessary to avoid undesirable consequences.



CE Mark
Signifies European Mark of technical conformity.

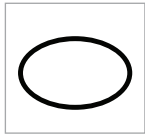
SYMBOL GLOSSARY



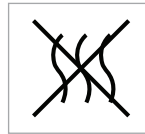
Sterilized using ethylene oxide indicates the medical device is provided sterile and has been sterilized using ethylene oxide.



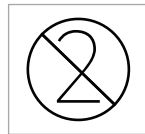
Do not re-sterilize indicates the medical device should not be re-sterilized



Single sterile barrier system
There is a single sterile barrier packaging. If torn the medical device is non sterile.



Non-Pyrogenic indicates the medical device is non pyrogenic.



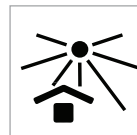
Do not re-use indicates the medical device is for single use only and must not be used more than once.



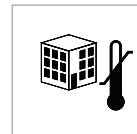
Keep Dry indicates the medical device needs to be protected from moisture.



Do not use if package is damaged indicates the medical device must not be used if the package holding the device is damaged or opened



Keep away from sunlight indicates the medical device shall not be stored in or exposed to sunlight



Storage Temperature indicates the medical device shall be stored in the temperature range indicated.



Transportation Temperature indicates the medical device shall be transported in the temperature range indicated.

FAQ

Why Can't I push down the NFIS Device trigger button?

Ensure your thumb is covering the entire surface of the trigger button for better leverage. Practice injecting in the injection test foam to get comfortable with the amount of pressure needed to press the trigger button successfully. If the issue persists, please contact to customer service team.

Does the injection device make a sound?

When injecting a medication, the device will make an audible click sound when the trigger button is pressed.

What are the Vial Adapters for?

The Vial Adapters are used to transfer the liquid drug / biologic from the medication vial into the cartridge of the Needle Free Injection System. Since NFIS Device does not use a needle to remove the drug / biologic from the vial, a Vial Adapter is needed to transfer the drug / biologic into the cartridge.

What are the Pre-filled Syringe Adapters for?

The pre-filled Syringe Adapters are used to transfer the liquid drug / biologic from the pre-filled syringe into the cartridge of the Needle Free Injection System.

How many times can the Vial Adapter be used?

The Vial Adapter is a disposable product intended to be used for one type of medication either a single dose or a multi-dose. Refer to 7.2 on Page 15.

How many times can the Pre-filled Syringe Adapters be used?

The Pre-filled Syringe Adapter is single use only.

Should I rotate my injection site?

Yes, the injection site should be rotated as directed by the physicians / healthcare professionals.

What is the best position for injecting?

The administrator of the injection must choose the appropriate position. However, must assure placement of NFIS Device at 90° & follow all the steps to perform injection as per Page 13.

FAQ

Does it bleed after receiving an injection?

Bleeding does not usually occur. Similar to needle injections, needle free injection system might cause some damage to the outer layer of skin. In rare instances, this might cause a pin-sized drop of blood to appear at the needle free injection site.

Why is some drug / biologic on the skin after the injection is complete?

When this occurs, it is because not all the medication has been administered. Residual medicine on the skin is caused by the device not being placed firmly enough on the skin and/or not being placed at 90° C. Press the NFIS Device firmly onto the injection site, until the skin is clearly sealed with the injection device. Hold the NFIS Device in place for 5 – 7 seconds to allow the medication to penetrate the skin completely.

What are the minimum and maximum quantities per application?

A minimum of 0.1 ml and a maximum of 0.5 ml of a liquid drug / biologic can be administered at one time.

Can the cartridge be used again?

No, the cartridge is intended to be single use only.

How do I clean the NFIS Device & Loader?

To prevent the cross contamination, the reusable NFIS Device & Loader should be disinfected with alcohol wipes outside of the device.

How do I store the NFIS Device?

Store the NFIS Device in the provided storage kitbox.

How do I dispose of the Cartridge, Vial Adapters, Pre-filled Syringe Adapters?

Dispose of the Cartridge, Vial Adapters, Pre-filled Syringe Adapters according to your local requirements or WHO Guidelines. Sharp disposal is not required as there are no sharp objects.

What temperature should the system be stored at?

The NFIS kit shall be ideally stored at temperatures between 10° C (50° F) - 40° C (104° F)



NEEDLE FREE INJECTION SOLUTIONS

**CUSTOMER SUPPORT
CUSTOMERSERVICE@INTEGRIMEDICAL.COM**

**TO ORDER, PLEASE EMAIL TO
ORDERS@INTEGRIMEDICAL.COM**

**FOR ANY COMPLAINTS PLEASE EMAIL TO
COMPLAINTS@INTEGRIMEDICAL.COM**

**FOR ANY SERIOUS ADVERSE EVENTS CONTACT INTEGRIMEDICAL AT SOS@INTEGRIMEDICAL.COM AND
INFORM THE RELEVANT COMPETENT AUTHORITY / REGULATORY BODY IN YOUR COUNTRY.**

WARRANTY INFORMATION

NFIS

The NFIS shall be covered under a warranty of 2 years from the date of purchase. The warranty shall cover any defects in material or workmanship under normal use. During the warranty period IntegriMedical will repair or replace the NFIS Device and/or the components. A handling and service fee may apply. To obtain warranty service, send an email with your NFIS Serial Number to **customerservice@integrimedical.com**

TRAINING ACKNOWLEDGEMENT

This is to acknowledge that the appointed IntegriMedical Distributor / Representative has provided training on the use of the Needle Free Injection System (NFIS).

Training Date: _____

IntegriMedical Dist. / Rep.

Name / Stamp / Sign

Hospital / Clinic / User

Name / Stamp / Sign

TEAR HERE

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NEEDLE FREE INJECTION SOLUTIONS

IntegriMedical LLC
7862 N County Road 100 E
Bainbridge IN 46105



IntegriMedical Private Limited
Survey No. 614,
Hissa No.10 & 11,
At Post Saswad, Taluka
Purandhar, Pune 412301,
Maharashtra, India
E-Mail: customerservice@integrimedical.com



Obelis s.a.
Boulevard General Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2.732.59.54
Fax: +(32) 2.732.60.03
E-Mail: mail@obelis.net

www.integrimedical.com