

# T h e S o f t S h o t



## Instructions For Use (IFU)

### Injex30 System

**INJEX**

**MD**

# T h e S o f t S h o t



**CAUTION:** Please read the instruction manual carefully! Consult your doctor before using for the first time.

# 1. Contents

1. Contents
2. General safety information
3. Purpose of use and Areas of application
4. Contraindications
5. System components
6. Combination with other products
7. Preparation of the Injex30 System
  - 7.1 Preparing the injector
  - 7.2 Filling the Injex Ampoule U-100/0.3ml
    - 7.2.1 From pen and cylinder cartridges with the Dosing Aid and the Transporter-adapter
    - 7.2.2 Filling the ampoule U-100 with a pen using the Pen-Adapter
    - 7.2.3 Filling the ampoule U-100 from injection bottles with the help of the Vial14/22-Adapter
    - 7.2.4 Filling the ampoule U-100 refractory vials using the Luer- Adapter
8. Product application
  - 8.1 Preparing for injection
  - 8.2 Performing the injection for diabetics & other users
9. Cleaning the injector
10. Disclaimer & Warranty
11. Troubleshooting
12. Disposal
13. Technical Data
14. Delivery specification
15. Explanation of symbols

## 2. General Safety Information



Please read these instructions for use carefully and understand all information thoroughly. If used by patients, they are asked to consult their doctor before using the Injex30 device for the first time.



Only use system components intended for the Injex30 system, especially accessories such as sterile disposable items with undamaged, unopened packaging.



The Injex30 is intended exclusively for subcutaneous administration of liquid drugs that can be administered using jet injection. Only medications with the needle-free injection system may be administered, for which pharmacokinetics and bioequivalence have been proven in clinical evaluations or observational studies.



Ensure compliance with the environmental and storage conditions for all components.



Multiple use of the sterile disposable accessories is prohibited. Likewise, none of the components may be reprocessed by resterilization (e.g., autoclaving).

Multiple use of the sterile medical devices may result in contamination by microorganisms. Multiple use of the ampoule may result in an injection being perceived as painful. Likewise, through multiple use, it is possible that the ampoule plunger may break, thereby impairing the functionality of the injector.

Multiple use of the adapters may result in inaccuracies when drawing up insulin and other drugs and contamination by microorganisms.



To minimize the risk of contamination when using the sterile ampoules, avoid any contact with the distal tip (pointing towards the body) before placing it on the injection site. The same applies to all openings of the sterile adapter and is also intended to prevent the risk of injuries from sharp and pointed adapter needles.



The reset box is only intended for tensioning the injector spring and must not be used to store the injector. To tension the injector, it can only be inserted into the reset box when the coloured locking ring is in the "safe" position.

### 3. Purpose of use and Areas of application

Injex30 is a needle-free injection system for the administration of selected liquid medicinal products suitable for jet injection into the subcutaneous adipose tissue under high pressure without the use of a needle. As an alternative to syringes with a needle, Injex30 enables low-pain, tissue-conserving and safe injection in many areas of application.

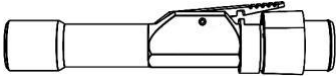
The system is suitable for self-use by adolescent or adult patients where a medical need is indicated, particularly for patients with needle phobia. Children aged 8 and above are only allowed to use Injex30 under adult supervision.

### 4. Contraindications

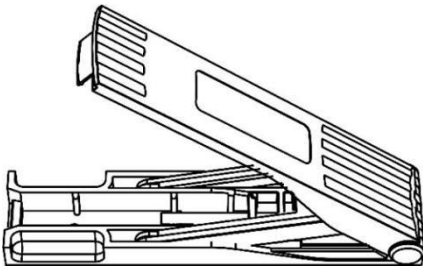
Injex30 must not be used for self-administration of systemically acting drugs (e.g. insulin) by cachectic patients, patients with severe visual impairment, severely restricted mobility of fingers / hands or an excessive tendency to form hematomas.

## 5. System components

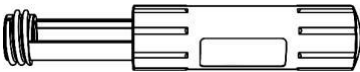
THE INJEX30 SYSTEM COMES WITH:



**Injector:** reusable, generates the precisely measured pressure through spring tension for subcutaneous injection.



**Reset Box (clamping box):** reusable, serves to tension the injector spring.



**Dosing Aid:** reusable, for the transfer of drugs from cylinder cartridges into the sterile single-use ampoules of the Injex30 system.



**CAUTION:** For sterility reasons and to avoid loss of function, the sterile-packed ampoules and adapters can only be used once and must then be disposed of.



To ensure sterility and eliminate the risk of injury, avoid any contact with the tip of the ampoule and avoid any contact with openings and needles of the adapters.

## AND THE FOLLOWING STERILE DISPOSABLES AS DEDICATED ACCESSORIES FOR THE INJEX30 SYSTEM:



**Ampoule U-100/0.3ml:**  
For the intake and administration of medication.



**Pen-Adapter:**  
Used for the transfer of e.g., insulin from a pen.



**Luer-Adapter:**  
Designed for the transfer of Medication from breakable ampoules.



**Vial14-Adapter:**  
Designed for the transfer of Medication from 14mm bottles.



**Transporter-Adapter:**  
Designed for the transfer of the medication from cylinder cartridges and is used in conjunction with the dosing aid.



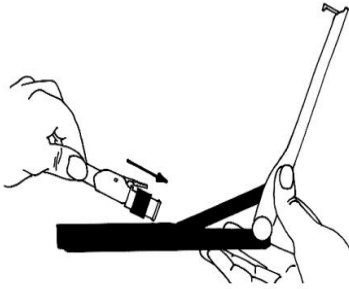
**Vial22-Adapter:**  
Designed for the transfer of Medication from 22mm bottles.

## 6. Combination with other products

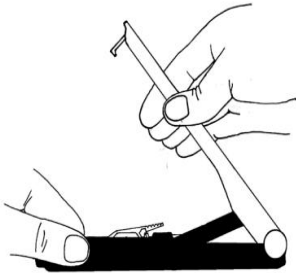
The Injex30 System is intended for the subcutaneous administration of liquid medications, which can be administered by jet injection. These medications are primarily packed in sterile primary packagings such as medicine bottles, cartridges (pen cartridge) or breakable ampoules and must be stored by the user according to storage and transport conditions. The user can carry out a transfer/filling of the ampoule using various adapters as a purpose-defined dedicated system accessory. The Injex ampoules and Injex adapters must only be used with the Injex30 injector.

# 7. Preparation of the Injex30 System

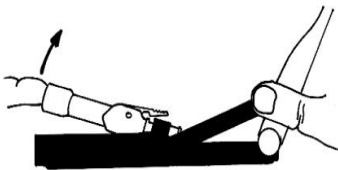
## 7.1 PREPARING THE INJECTOR



1. Place the injector into the reset box. The injector's green locking ring must be in the "safe" position.



2. Close the lid of the reset box.



3. Open the lid of the reset box and remove the cocked and secured injector from the reset box.

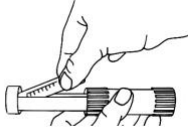


**CAUTION:** The injector can only be inserted into the reset box when the green locking ring of the injector is in the "safe" position.

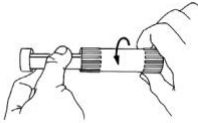
## 7.2 FILLING THE INJEX AMPOULE U-100/0.3ml

### 7.2.1 FROM PEN & CYLINDER CARTRIDGES WITH THE DOSING AID AND THE TRANSPORTER-ADAPTER

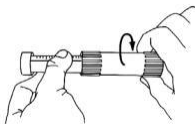
#### Preparation of the Dosing Aid and the Transporter-Adapter



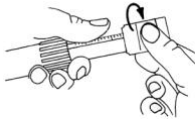
1. Turn the green handle of the dosing aid until the pen or cylinder cartridge can be inserted into the dosing aid chamber.



2. Take the cartridge and place it into the dosing aid chamber with the cap facing outwards.



3. To ensure that the cartridge is securely in place, turn the green handle of the dosing aid until the piston of the dosing aid lightly touches the rubber seal on the cartridge.



4. Take the transporter-adapter out of the sterile packaging. Screw the adapter onto the dosing aid as securely as possible. The needle of the adapter must pierce the rubber seal of the cartridge. After using the adapter once, dispose of it in the normal household waste.

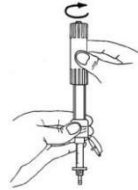
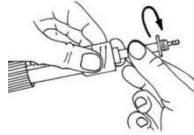
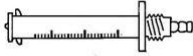
To ensure sterility and prevent the risk of injury:

- Avoid any contact with the ampoule tip!
- Avoid any contact with the openings and needles of the adapter!



**CAUTION:** The adapter needle is sharp and pointed and can cause injuries:

## Filling the Injex Ampoule U-100/0.3ml



1. Take an ampoule U-100 of the Injex30 system out of the sterile packaging and push the ampoule piston completely into the ampoule.

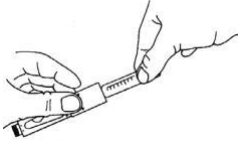
2. Open the lid of the transporter-adaptor and screw the ampoule into the adapter as tightly as possible.

3. Turn the handle of the dosing aid until the ampoule contains the desired dose without air bubbles.

**Note:** After filling the ampoule, turn the handle of the dosing aid back a little bit to prevent the inner piston from pushing down the rubber seal of the cartridge. This way no more medication can escape.

## 7.2.2 FILLING THE AMPOULE U-100 WITH A PEN USING THE PEN-ADAPTER

### Pen-Adapter preparation



1. Pick up your pen and insert the pen cartridge as usual.



2. Remove the Pen-Adapter from its sterile packaging.

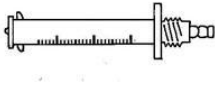


3. Screw the closed Pen-Adapter onto the thread of your pen.

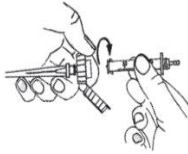
To ensure sterility and prevent the risk of injury:

- Avoid any contact with the ampule tip!
- Avoid any contact with openings and needles of the adapters!

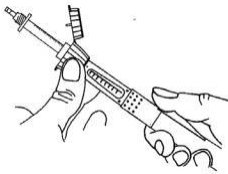
## Filling the Injex Ampoule U-100/0.3ml



1. Take an ampoule U-100 from the sterile packaging and press the ampoule piston completely into the ampoule.



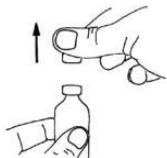
2. Open the lid of the pen-adaptor and screw the ampoule U-100 into the adaptor until it stops.



3. Fill the ampoule by setting the required units on the pen as usual, pressing the trigger of the pen and holding it down for a few seconds. After using the adaptor once, dispose of it in the normal household waste.

## 7.2.3 FILLING THE AMPOULE U-100 FROM INJECTION BOTTLES WITH THE HELP OF THE VIAL14/22-ADAPTER

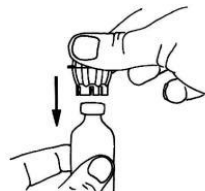
### Preparation of Vial14/22-Adapters



1. Take a medication bottle out of its packaging and remove the protective cap.



2. Take a Vial-adapter out of its sterile packaging (Vial14-Adapter or Vial22-Adapter depending on the diameter of the bottle neck).

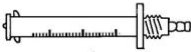


3. Use the needle of the vial-adapters to pierce the rubber seal of the medicine bottle. Make sure that the adapter is positioned accurately and tightly.

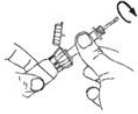
To ensure sterility and to prevent the risk of injury:

- Avoid any contact with the ampoule tip!
- Avoid any contact with the openings and needles of the adapter!

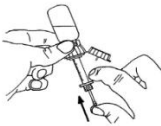
## Filling the Injex Ampoule U-100/0.3ml



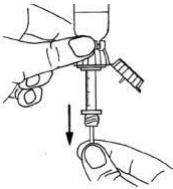
1. Take one ampoule U-100 out of the sterile packaging and pull the ampoule piston back about halfway.



2. Open the lid of the Vial14/22-Adapter and screw the ampoule U-100 into the adapter as tightly as possible.



3. Turn the bottle including the ampoule U-100 over and push the ampoule piston completely into the ampoule U-100.



4. Pull the ampoule piston back slowly until the desired dose has been drawn up. If air bubbles are trapped inside the ampoule U-100, push the piston all the way back into it and draw the desired dose again. After using the adapter once, dispose of it in the normal household waste.

## 7.2.4 FILLING THE AMPOULE U-100 FROM BREAKABLE AMPOULES USING THE LUER-ADAPTER

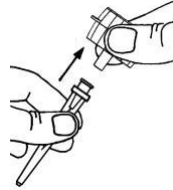
### Preparation of the Luer-adapter



1. Take a sterile cannula with a Luer connection from its sterile packaging.



2. Take the Luer-Adapter from its sterile package.



3. Push the sterile cannula with the Luer connection onto the Luer cone of the adapter.

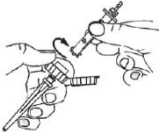
To ensure sterility and to prevent the risk of injury:

- Avoid any contact with the ampoule tip!
- Avoid any contact with the openings and needles of the adapter!

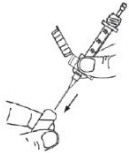
## Filling the Injex Ampoule U-100/0.3ml



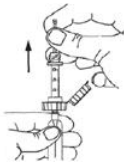
1. Take one ampoule out of the sterile packaging.



2. Open the lid of the Luer-adapter and screw the ampoule U-100 into the adapter as tightly as possible.



3. Remove the protective cap from the sterile cannula and insert the needle with the Luer-Adapter into the desired medication container (e.g. breaking ampoule).



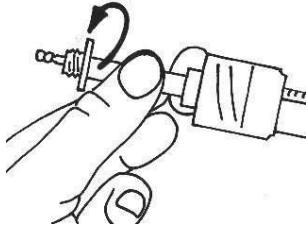
4. Fill the ampoule by slowly withdrawing the ampoule piston until the desired dose has been drawn up. If air bubbles are trapped inside the ampoule U-100, push the piston all the way back into it and re-draw the desired dose. After using the adapter once, dispose of it in the normal household waste.



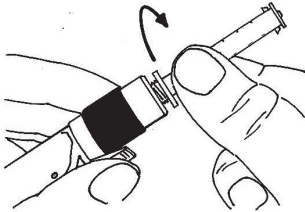
**CAUTION:** If a larger dose than desired has been drawn up, unscrew the Injex ampoule U-100/0.3ml from the bottle and push the ampoule piston up to remove any excess drug or trapped air bubbles.

## 8. Product application

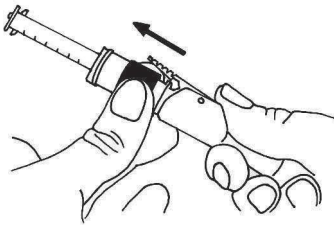
### 8.1 PREPARING FOR INJECTION



1. Unscrew the filled Injex ampoule U-100/0.3ml from the adapter and close the lid of the adapter.



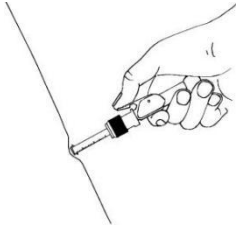
2. Now turn the filled ampoule with the piston first all the way to the end into the large opening of the injector. Note: The last, somewhat more difficult turn overcomes a resistance that deactivates the first safety mechanism.



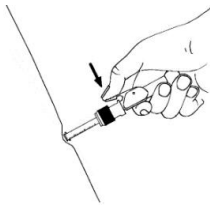
3. Slide the green locking ring forward into the "safety off" position. The second safety mechanism is now deactivated and the injector is ready for injection.

## 8.2 PERFORMING THE INJECTION FOR DIABETICS & OTHER USERS

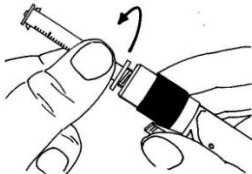
The injector can be placed on all common parts of the body that are suitable for subcutaneous injection. Most notably arms, legs, abdomen, hips, and buttocks. The choice of the injection point is very important. Therefore, always choose a part of the body with a particularly large amount of subcutaneous fat.



1. Hold the injector vertically (**90° angle**) to the injection site and apply pressure until the skin is clearly indented and the ampoule head is completely enclosed by the skin.



2. Press the trigger and leave the injector on the injection site for another 2 seconds after it has been triggered with sustained pressure.

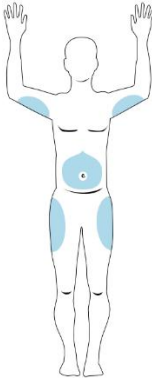


3. Remove the ampoule U-100 from the injector and dispose of it via normal household waste. Push the green locking ring of the injector back into the "safe" position.

**Avoid stretching the skin at the injection site immediately after the injection.**

**Note for diabetics:** Insulins with different duration of action can be mixed and administered with an Injex ampoule U-100/0.3ml after consultation with your doctor and in accordance with the manufacturer's instructions.

## ESPECIALLY RECOMMENDED INJECTION POINTS:



**Arms:** Place your arm on the edge of the table. Relax the muscles and twist your arm forward to reveal the fatty tissue. Place the injection in the middle between the elbow and shoulder in the back of the upper arm. That area is particularly rich in fatty tissue.

**Belly:** Stand up straight and put the injector on the lateral abdominal skin (level with the navel). Never inject in the middle of the abdomen.



**Legs:** Sit upright on a chair exposing your thighs. Relax the muscles and apply the injection on the upper side of the thigh, in the middle between the knee and hip.

**Hips and buttocks:** Sit down exposing hip or buttocks for easier access. Apply the injector at a 90° angle as described in 8.2.



**CAUTION:** Patients who mix two different insulins must not change the order of the insulins to be mixed as specified by the doctor or change the type of application or the model of the injector without first discussing this with the doctor in charge. Failure to comply with this CAUTION can lead to dosing errors!



**CAUTION:** Do not insert anything other than the ampoule U-100 into the open end of the injector.

## 9. Cleaning the injector

Only the reusable system components such as Injector, Reset Box and Dosing Aid are to be freed from dust, dirt and drug residues by occasional external cleaning. This can be done by wiping them off with a damp cloth using a solvent-free cleaning agent (e.g. tenside).



Multiple use of the sterile disposable items as system accessories is prohibited. Likewise, reprocessing by re-sterilization (e.g. autoclaving) must not be carried out on any of the system components or accessories.

## 10. Disclaimer & Warranty

The manufacturer of this medical device assumes no liability for direct or consequential damage if:

- the Injex30 or its accessories are improperly used, prepared or maintained,
- Instructions and regulations laid out in the instructions for use are not observed,
- unauthorized persons carry out repairs, adjustments or changes to the device, components or accessories,
- unauthorized persons open the device,
- the prescribed instructions for cleaning and storage are not obeyed.

## WARRANTY

The Injex30 system has been carefully manufactured and has been delivered in perfect condition. The Injex30 system comes with a 3-year warranty for its functionality.

### **Customer Service:**

Injex Pharma GmbH  
Haynauer Straße 72A,  
12249 Berlin, Germany  
Email: [info@injex.de](mailto:info@injex.de)



# 11. Troubleshooting

The reusable system components of the Injex30 system (Injector, Reset Box and Dosing Aid) are maintenance-free for the user.

Should technical malfunctions occur which cannot be eliminated by the following measures, or in the event of a complaint, please contact our service hotline:

Tel: +49 30 57799035 (when calling, please have the serial number ready, which is located on the bottom of the injector)  
 Email: info@injex.de

Problem	Cause	Solution
Injector does not trigger	The ampoule U-100 is not properly screwed in	Screw the ampoule U-100 firmly onto the injector
	Ampoule U-100 not filled	Fill the ampoule U-100
	No ampoule U-100 screwed on	Screw on the ampoule U-100
	Locking Ring is in "safe" position	Slide Locking Ring to "safe off" position
Injector cannot be inserted into the Reset Box	Injector not secured	Slide Locking Ring to "safe" position
	Injector or box heavily dirty	Cleaning
	Injector in wrong position	Insert Injector with trigger facing to the top and the open end towards the direction of the hinge
Drug will not release	Ampoule U-100 opening blocked	Use a new ampoule U-100
Reset Box does not load the Injector	Injector or reset box heavily dirty	Cleaning
	Reset Box not completely closed	Repeat the motion, be sure to properly close reset box
	Injector already cocked	Injector ready to be used

## 12. Disposal

At the end of the useful life of the reusable system components, please dispose of them properly and separately or return them to the manufacturer. The sterile disposable items (system accessories) must be disposed separately with regular household waste after use.

## 13. Technical data

<b>Transport and storage conditions</b>	- dry and dust-free - temperature range +5 to + 35 °C - protect from moisture
<b>Injector service life</b>	3 years or 5000 uses

### Injex Ampoule U-100/0.3ml

















Dosing range	0.05 to 0.3 ml (30 IU insulin U-100 ampoule)
Dosing accuracy	± 2% at dose <0.15 ml (corresponds to <15 IU insulin U-100) ± 1.5% at dose > 0.15 ml (corresponds to > 15 IU insulin U-100)

Graduation: 1 graduation = 0.01 ml (corresponds to 1 IU insulin U-100)

## 14. Delivery specification

<b>Injex30 System / Box or Bag</b>	1 Piece	REF 338011002
in the box or bag, it includes:		
Injex30 Injector	1 Piece	REF 338011001
Injex Dosing Aid	1 Piece	REF 338012000
Injex Reset Box	1 Piece	REF 338013000
Injex Instructions For Use (IFU)	1 Piece	REF 830438013

# 15. Explanation of symbols

	CAUTION!		Single sterile barrier system
	One-time product, do not use more than once		Sterilization by irradiation
	Do not use if the package is damaged		LOT marking
	Humidity range		Serial number
	Temperature range		Reference number
	Expiry date		Keep away from moisture
	Caution, instructions for use		Reference to the name of the manufacturer
	Medical Device		Date of manufacture

## Additional Note:

In accordance with Regulation (EU) 2017/745 (MDR) Annex I, Chapter III, point 23.4z), a notice is provided to the user and/or patient that all serious incidents that have occurred in relation to the product must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

# T h e S o f t S h o t

**CE** 0297

**SRN:** DE-MF-000006766  
**IFU Version:** IFU\_R11\_2026\_NSC



**INJEX**PHARMA

Haynauer Straße 72A,  
12249 Berlin, Germany

[info@injex.de](mailto:info@injex.de)  
[www.injex.de](http://www.injex.de)

**MD**