

T h e S o f t S h o t



Instructions for use INJEX 30 System

INJEX



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

1. Contents

1.	Contents	2
2.	General safety information	3
3.	Purpose of use, areas of application	4
4.	Contraindications	4
5.	System components	6
6.	Combination with other products	7
7.	Preparation of the Injex 30 system	8
7.1	Prepare the injector	8
7.2.	Filling the ampoule U-100	9
7.2.1	From pen and cylinder cartridges with the dosing aid and the transporter-adapter	9
7.2.2.	Filling the ampoule with a Pen using the Pen adapter	10
7.2.3.	From injection bottles using the Vial-Adapter 14 or 22	11
7.2.4.	From break ampoules using the Luer adapter	13
8.	Product application	15
8.1	Preparing for injection	15
8.2	Performing the injection for diabetics & other users	16
9.	Cleaning	16
10.	Disclaimer & Warranty	16
11.	Troubleshooting	17
12.	Disposal	21
13.	Technical Data	21
14.	Delivery specification & accessories	<u>21</u>
15.	Explanation of symbols	22

2. General safety information



Please read these instructions for use carefully and carefully observe all information. If used by patients, they are asked to consult their doctor before using the INJEX 30 system for the first time.



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



The INJEX 30 system is intended exclusively for the subcutaneous administration of liquid drugs that can be administered using jet injection. Only medications with the needleless injection system may be administered of which pharmacokinetics and bioequivalence have been proven in clinical evaluations or observational studies



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



Multiple use of the sterile disposables as system accessories is excluded. Likewise, none of the system components may be reprocessed by reesterilization (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, it is possible that the ampoule plunger may break, thereby impairing the functionality of the injector.

Multiple use of the adapters may result in the desired amount of insulin not being drawn up 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 colored locking ring is in the "safe" position.

3. Purpose of use, areas of application

INJEX 30 is a needleless 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, the INJEX 30 system enables low-pain, tissue-conserving and safe injection in many areas of application.

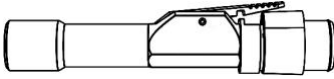
The system is suitable for self-use by adolescent or adult patients where a medical need is indicated, particularly for patients with needle phobia. Children aged 8 and over are only allowed to use it themselves under adult supervision.

4. Contraindications

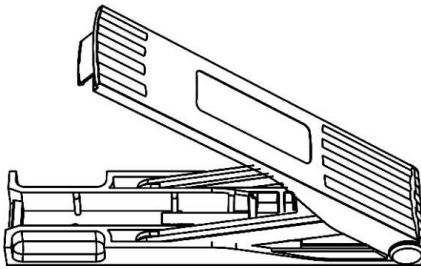
The INJEX 30 system must not be used for self-administration of systemically acting drugs (e.g. insulin) by cachectic patients, patients with severe visual impairment, severely restricted mobility of fingers / hands or an excessive tendency to form hematomas.

5. System components

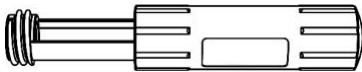
THE INJEX 30 SYSTEM CONSISTS OF:



Injector: reusable, generates the precisely measured pressure through spring tension for the 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 INJEX 30 system.



WARNING: 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 INJEX 30 SYSTEM:



Ampoule U-100:

For the intake and administration of medication.



Pen-Adapter:

Is used for the transfer of e.g., insulin from a pen.



Luer-Adapter:

is designed for the transfer of medication from breaking ampoules.



Vial-Adapter 14/22:

designed for the transfer of medication from 14mm/22mm bottles.



Transporter-Adapter:

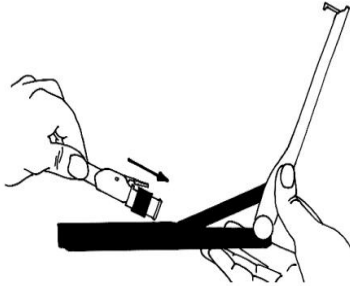
for the transfer of the medication from cylinder cartridges and is used in conjunction with the dosing aid.

6. Combination with other Products

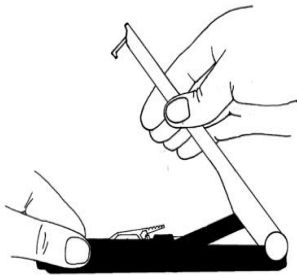
The INJEX 30 System is intended for the subcutaneous administration of liquid medications, which can be administered by jet injection. These medications are primarily packed in sterile primary packaging's such as medicine bottles, cartridge (pen cartridge) or crushing ampoules and must be stored by the user in according to storage and transport conditions. The user can carry out a transfer/filling of the INJEX ampoule U-100 using various adapters as a purpose-defined system accessory dedicated system accessory. The Injex ampoules and Injex adapters should only be used with the Injex 30 injector.

7. Preparation of the INJEX30 system

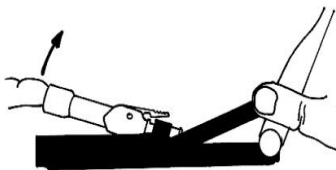
7.1 PREPARATION OF THE INJECTOR



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.



WARNING: The adapter needle is sharp and pointed and can cause injuries:

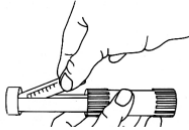


WARNING: The injector can only be inserted into the reset box when the green locking ring of the injector is in the "safe" position.

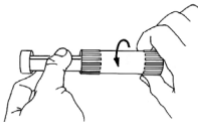
7.2. Filling the ampoules

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

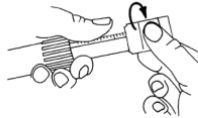
Preparation of the dosing aid and the Transporter-Adapter



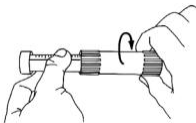
1. Turn the green handle of the dosing aid until the pen or cylinder cartridge can be inserted into the dosing aid chamber.



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.

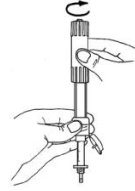
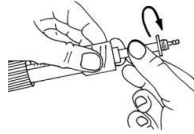
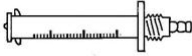


4. Take the transporter adapter out of the sterile packaging. Screw the adapter onto the dosing aid as far as it will go. The needle of the adapter must pierce the rubber seal of the cartridge. After using the adapter once, dispose of it in the normal household waste.

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!

Filling the Ampoule U-100



1. Take an ampoule U-100 of the INJEX30 system out of the sterile packaging and push the ampoule piston completely into the ampoule

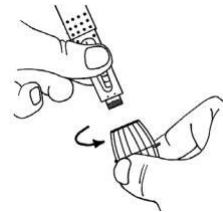
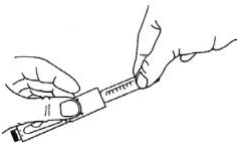
2. Open the lid of the transporter adapter and screw the ampoule into the adapter as far as it will go.

3. Turn the handle of the dosing aid until the desired dose is free of air bubbles in the ampoule U-100.

Note: After filling the ampoule U-100, 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.

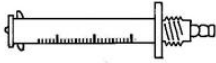
2. Remove the Pen-Adapter from its sterile packaging.

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

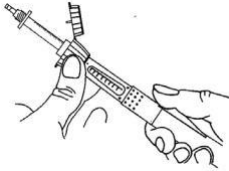
To ensure sterility and prevent the risk of injury:

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

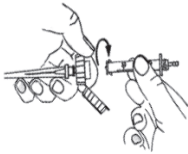
Filling the Ampoule U-100



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



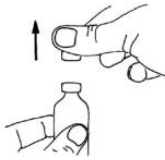
2. Open the lid of the pen-adapter and screw the ampoule U-100 into the adapter until it stops



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 adapter 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 VIAL ADAPTER- 14 or 22

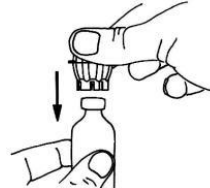
Preparation of Vial adapters- 14 or 22



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



2. Take a Vial adapter out of its sterile packaging (Vial adapter 14 or 22 depending on the diameter of the bottle neck).

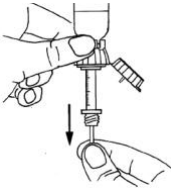
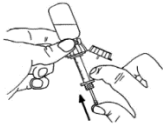
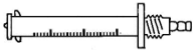


3. Use the needle of the Vial-adapters 14 or 22 to pierce the rubber seal of the medicine bottle. Make sure that the adapter is positioned accurately and tightly.

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 ampoule U-100



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 Vial – adapters 14 or 22 and screw the ampoule U-100 into the adapter as far as it will go.
3. Now turn the bottle including the ampoule U-100 over and push the ampoule piston completely into the ampoule U-100.
4. Now 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. FILL THE AMPOULE REFRACTORY VIALS WITH HELP OF THE LUER ADAPTER

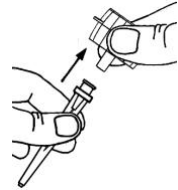
Preparation of the Luer-adapter



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



2. Take the Luer 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!
-

Befüllen der Ampulle U-100



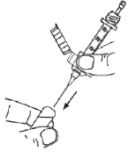
1. Take one ampoule out of the sterile packaging.



2. Open the lid of the Luer adapter and screw the ampoule U-100 into the adapter as far as it will go.



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).



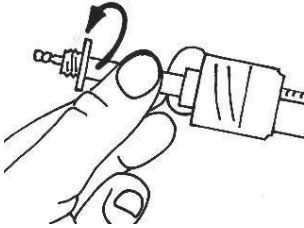
4. Fill the ampoule by slowly withdrawing the ampoule piston until the desired dose has been drawn up. If air bubbles are trapped inside the ampoule U-100, push the piston all the way back into it and re-draw the desired dose. After using the adapter once, dispose of it in the normal household waste.



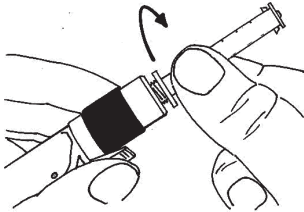
WARNING: If a larger dose than desired has been drawn up, unscrew the INJEX ampoule U-100 from the bottle and then push the ampoule piston up to remove any excess drug or trapped air bubbles.

8. PRODUCT APPLICATION

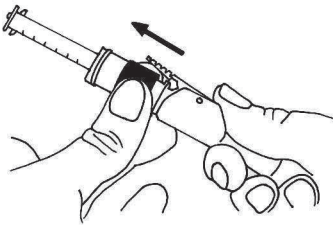
8.1. PREPARING FOR INJECTION



1. Unscrew the filled ampoule U-100 from the adapter and close the lid of the adapter.



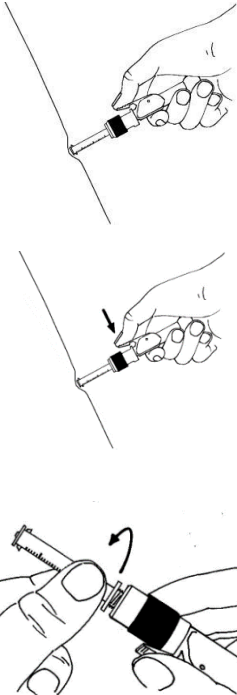
2. Now turn the filled ampoule U-100 with the piston first all the way to the end into the large opening of the injector.
Note: The last, somewhat more difficult turn overcomes a resistance that deactivates the first safety mechanism.



3. Slide the green locking ring forward into the "safe 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. The most common areas to give injections are the arms, legs, abdomen, hips, and buttocks. The choice of the injection point is very important. Therefore, choose a part of the body with particularly high amount of subcutaneous fat.

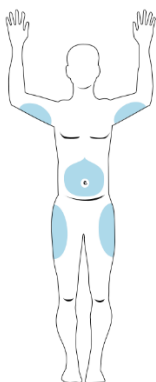


1. Hold the injector vertically (90 ° angle) on the injection site with pressure until the skin is clearly indented and the ampoule head is completely enclosed by the skin.
2. Press the trigger and leave the injector on the injection site for another 2 seconds after it has been triggered with sustained pressure.
3. Turn the ampoule U-100 off the injector and dispose of it with 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 ampoule U-100 after consultation with the 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, as that area is particularly rich in fatty tissue.

Belly: Stand up straight and put the injector on the Lateral abdomen skin (in Height of the belly fold). Never inject in the middle of the abdomen.



Legs: Sit on a chair so that your thigh is also on top. 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 on a chair in a way that either hip or buttocks are easily accessible.



WARNING: 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 warning can lead to dosing errors.!



WARNING: 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 by wiping them off with a damp cloth using a solvent-free cleaning agent (e.g. tenside).



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

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 in these operating instructions are not observed,
- unauthorized persons carry out repairs, adjustments or changes to the device 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 is technically perfect: Delivered free condition. The guarantee performance for the functionality of the INJEX30 system is 3 years.

Address for complaints /Feedback:
INJEX Pharma GmbH
Beeskowdamm 6
14167 Berlin
customerservice@injex.de

11. Troubleshooting

The reusable system components of the Injex 30 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 (0) 030 5858382-75 (when calling, please have the serial number ready, which is located on the bottom of the injector.)
 eMail: customerservice@injex.de

problem	root cause	solution
Injector does not trigger	The ampoule U-100 is not tight	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
	Circlip is in "safe" position	Slide Circlip to "safe" position
Injector can not in the reset box insert	<i>Injector not secured</i>	Slide Circlip 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 released	Ampoule U-100 opening blocked	Use a new ampoule U-100
Reset box loads the Injector not	Injector or reset box heavily dirty	top and the open end towards
	Reset box not completely closed	
	Injector already cocked	

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

Transport and storage conditions:	dry and dust-free in the temperature range +5 to + 35 ° C, protect from moisture
Injector service life	3 years bzw. 5000 trips

INJEX Ampulle U-100

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 (corresponding to > 15 IU insulin U-100)

















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

14. Delivery specification & accessories

1 piece - INJEX30 system
(injector, reset box, dosing aid) +
Instructions for use, in the outer

box:	1 Stück	REF 338 011 0 0 2
INJEX Injector	1 Stück	REF 338 010 0 0 1
INJEX Ampoule U-100 / 0.3ml	50 Stück	REF 546 000 4 0 0
INJEX Transporter- Adapter	20 Stück	REF 511 000 7 0 0
INJEX Pen- Adapter	20 Stück	REF 511 000 5 0 0
INJEX Vial-Adapter 14	20 Stück	REF 511 000 4 0 0
INJEX Vial-Adapter 22	20 Stück	REF 511 000 8 0 0
INJEX Luer -Adapter	20 Stück	REF 511 000 6 0 0
INJEX Dosing aid	1 Stück	REF 338 012 0 0 0
INJEX reset box	1 Stück	REF 338 013 0 0 0

15. Explanation of symbols

	Warning!		Single sterile barrier system
	One-time product, no use several times		Sterilization by irradiation
	don't use if damaged package		Lot marking
	Humidity limitation		Serial number
	Temperature limit		Reference number
	expiry date		Keep away from moisture
	Caution, instructions for use look at instruction		Reference to the name of the manufacturer
	Medical Device		Date of manufacture

T h e S o f t S h o t



0297

SRN: DE-MF-000006766

Version number:
R08_2022_LAN



INJEXPHARMA GMBH

Beeskowdamm 6
14167 Berlin

customerservice@injex.de
www.injex.de