

T h e S o f t S h o t



Instructions for use INJEX 30

INJEX

T h e S o f t S h o t

Notes:



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

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



When using the sterile ampoules, avoid any contact with the distal tip (pointing towards the body) before placing it on the injection site because of the risk of contamination. The same applies to contact with all openings of the sterile adapter, including to avoid the risk of injury 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-sparing 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 in patients with needle phobia. Children aged 8 and over are only allowed to use it themselves under adult supervision.

The administration of topically acting liquid medicaments such. B. Local anesthetics reserved exclusively for the attending physician. For dental use, INJEX 30 is only suitable for infiltration anesthesia in the anterior region in connection with the SiliTop (accessory) in the fixed, intact gingiva.

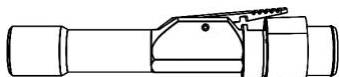
4. Contraindications

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.

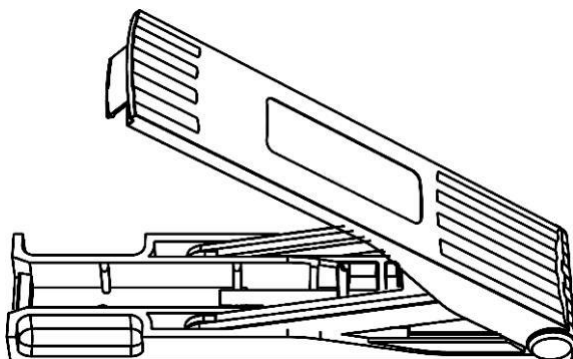
Topical administration of local anesthetics by the dentist must not be carried out in infected and / or inflamed gums, in the region between the 1st and 2nd premolar or directly via nerve outlet openings (e.g. mental nerve).

5. System components

THE INJEX 30 SYSTEM CONSISTS OF:



Injector: reusable, to generate the precisely measured pressure by means of spring force 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: The sterile packaged **ampoules and adapters** can only be used once for reasons of sterility and to avoid loss of functionality and must then be disposed of.



To ensure sterility and to exclude the risk of injury, avoid any contact with the **ampoule tip** and avoid any contact with openings and needles of the **adapter**.

AND THE FOLLOWING STERILE DISPOSABLES AS DEDICATED ACCESSORIES FOR THE INJEX 30 SYSTEM:



Ampoule:

For the intake and administration of drugs.



Luer-Adapter:

is designed for the transfer of drugs from crushed ampoules.



Dosing aid-

Adapter:

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



Pen-Adapter:

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



Bottle-Adapter

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



SiliTop:

For combined use with Ampoule of the INJEX 30 System for dental application of local anaesthetics.

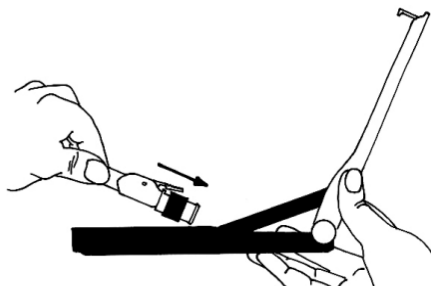


6. Combination with other Products

The INJEX 30 System is intended for the subcutaneous administration of liquid medications, which can be administered by jet injection. These Medicines are primarily packed in sterile primary packagings such as medicine bottle, cartridge (pen cartridge) or crushing ampoule 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 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 INJECTORS



1. Place the injector in 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.

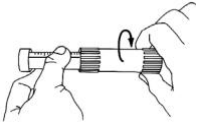


WARNING: The injector can only be inserted into the reset box when the green locking ring of the injector is in the "safe" position.

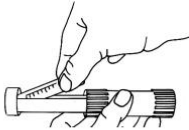
7.2. Filling the ampoules

7.2.1. FROM PEN & CYLINDER CARTRIDGES WITH THE DOSING AID

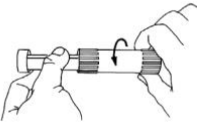
Preparation of the dosing aid



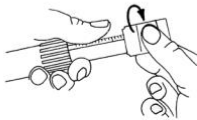
1. Turn the green handle of the dispensing aid until the pen or cylinder cartridge can be inserted into the dispensing aid chamber.



2. Take the cartridge and place it in the dispensing aid chamber with the cap facing outwards.



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

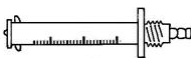


4. Take the dosing aid adapter out of the sterile packaging. Screw the adapter onto the dispensing aid as far as it will go. The needle of the adapter must pierce the rubber seal of the cartridge.

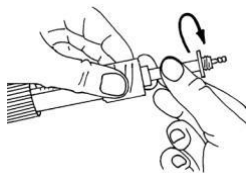
To ensure sterility and to exclude the risk of injury:

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

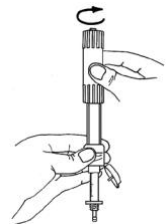
Filling the ampoule



1. Take an ampoule of the INJEX30 system out of the sterile packaging and push the ampoule plunger completely into the ampoule.



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

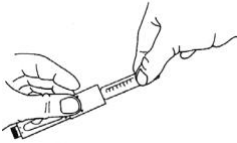


3. Turn the handle of the dosing aid until the desired dose is free of air bubbles in the ampoule.

Note: After filling the ampoule, turn the handle of the dosing aid what back so that the inner piston does not hit the rubber seal of the cartridge presses so that no more medication can escape.

7.2.2. FILLING THE AMPOULE 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.

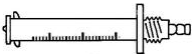


3. Screw the closed pen adapter onto the thread of your pen.

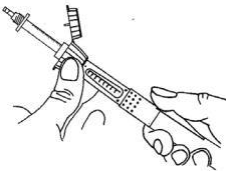
To ensure sterility and eliminate the risk of injury:

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

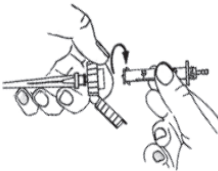
Filling the Ampoule



1. Take an ampoule 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 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.

7.2.3. FILLING THE AMPOULE FROM INJECTION BOTTLES WITH THE HELP OF THE BOTTLE ADAPTER

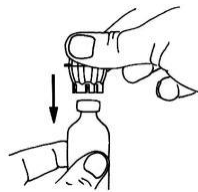
Preparation of bottle adapters



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



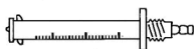
2. Take a bottle adapter out of its sterile packaging (bottle adapter 14 or 22 depending on the diameter of the bottle neck).



3. Use the needle of the bottle adapter to pierce the rubber stopper of the medicine bottle. Make sure that the bottle adapter is firmly seated.

To ensure sterility and to exclude the risk of injury:

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

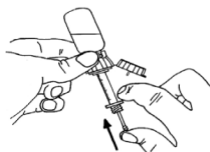


Filling the ampoule

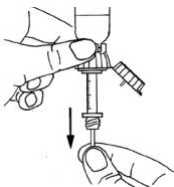
1. Take one ampoule out of the sterile packaging and pull the ampoule plunger back about halfway.



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



3. Now turn the bottle including the ampoule over and push the ampoule plunger completely into the ampoule.



4. Now pull the ampoule plunger back slowly until the desired dose has been drawn up. If air bubbles are trapped, push the ampoule plunger all the way back into the ampoule and draw the desired dose again.

7.2.4. FILL THE AMPOULE REFRACTORY VIALS WITH HELP OF THE LUER ADAPTER

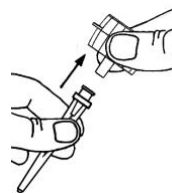
Preparation of the Luer adapter



1. Take a sterile cannula with an Luer connector from its sterile packaging.



2. Take the Luer from its sterile package.



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

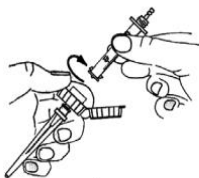
To ensure sterility and to exclude the risk of injury:

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

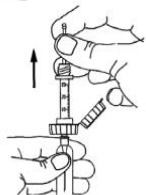
Filling the INJEX ampoule



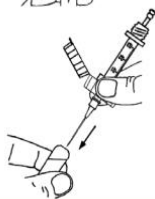
1. Take one ampoule out of the sterile packaging.



2. Open the lid of the Luer adapter and screw the ampoule into the adapter as shown 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. breakable ampoule).



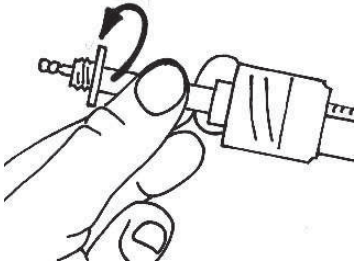
4. Fill the ampoule by slowly withdrawing the ampoule plunger until the desired dose has been drawn up. If air bubbles are trapped, push the plunger all the way back into the ampoule and re-draw the desired dose.



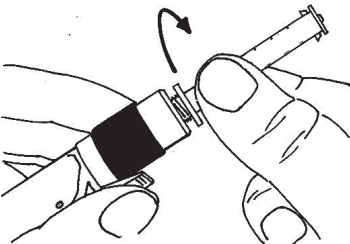
WARNING: If a larger dose than desired has been drawn up, unscrew the INJEX ampoule from the bottle and then push the ampoule plunger up to remove any excess drug or trapped air bubbles.

8. PRODUCT APPLICATION

8.1 PREPARING FOR INJECTION

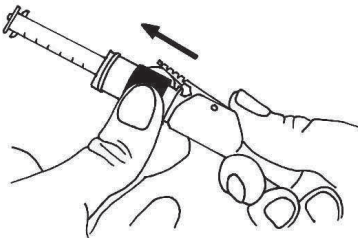


1. Unscrew the filled ampoule from the adapter and close the lid of the adapter.



2. Now turn the filled ampoule with the Push the piston up to the stop in the large opening at the end of the injector.

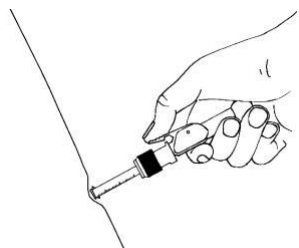
Note: The last, somewhat more difficult turn overcomes a resistance that deactivates the first safety mechanism.



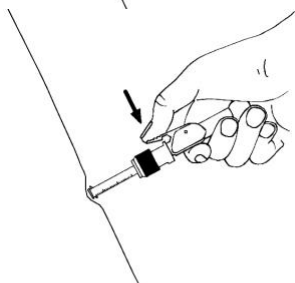
3. Slide the green locking ring forward into the "safe off" position. The second safety mechanism is now deactivated and the injector is ready for injection.

8.2. PERFORMING THE INJECTION FOR DIABETICS & OTHER USERS

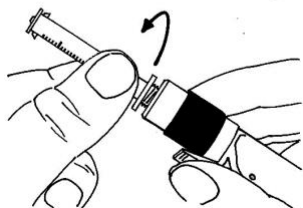
The injector can be placed on all common parts of the body that are suitable for subcutaneous injection. The most common injections are given to the arms, legs, abdomen, hips, and buttocks. The choice of the injection point is very important. Therefore, choose a part of the body with particularly pronounced 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.



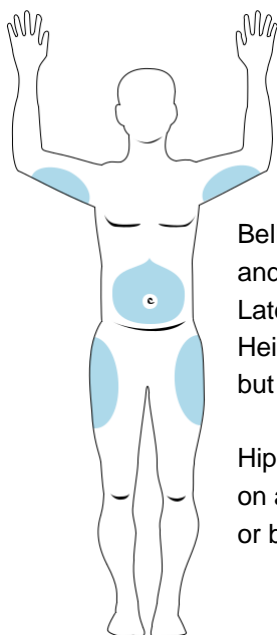
3. Turn the ampoule off the injector and dispose of it with normal household waste. Push the green locking ring of the injector back into the "safe" position.

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 after consultation with the doctor and in accordance with the manufacturer's instructions.

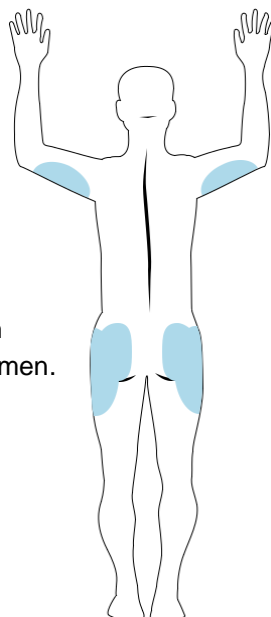
ESPECIALLY RECOMMENDED INJECTION POINTS:

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 the fatty tissue is particularly pronounced here.



Belly: Stand up straight and put the injector on the Lateral abdomen skin (in Height of the belly fold). Inject each but never in the middle of the abdomen.

Hips and buttocks: Sit like this on a chair that is either hip or buttocks are easily accessible.



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.

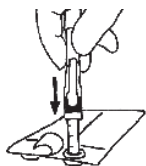


WARNING: Patients who mix two different insulins must not change the order of the insulins to be mixed as specified by the doctor or change the type of application or the model of the injector without first discussing this with the doctor in charge. Failure to observe this warning can lead to dosing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

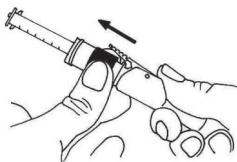


WARNING: Do not insert anything other than the ampoule into the open end of the injector.

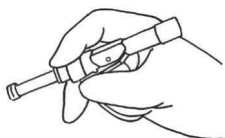
8.3 PERFORMING THE INJECTION THE DENTIST (DENTAL APPLICATION)



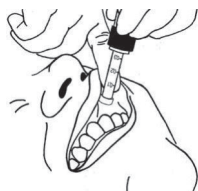
1. Remove the paper seal from the blister packaging of a SiliTop. Push the head of the ampoule all the way in the SiliTop. Pull open the injector with the SiliTop on the ampoule head out of the packaging.



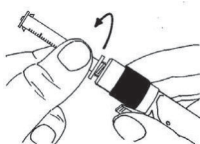
2. Slide the green locking ring forward in "Safe off" position. The injector is now ready to inject



3. The injector is in between your thumb and forefinger to hold the hand. The trigger should be with the Thumbs are pressed.



4. The injector is perpendicular (90° angle) to the fixed Gingiva of the tooth to be treated under light Put pressure on. Now prepare your patient **on the trigger sound in front of reflex reactions to avoid.** Confirm the trigger and release the injector (with sustained pressure) two seconds on the mucou skin.



5. Unscrew the vial from the injector and discard this with normal household waste. Push the green locking ring of the injector to the rear in the "safe" position. Put the backed up and unstressed injector back into the Injex pocket.



WARNING: The ampoule must be placed at an angle of 90 ° on the fixed gingiva directly above the tooth to be anesthetized, this requires a defined area of application (infiltration anesthesia).



WARNING: Please note the general contraindications for local anesthesia. INJEX should not be injected through nerve exit points (e.g. Mentalis).



WARNING: Never use INJEX in the jaw area and over bones without SiliTop. The SiliTop is a sterile single-use product.

9. Cleaning the injector

Only the reusable system components injector, reset box and dosing aid are to be freed from dust, dirt and drug residues by occasional external cleaning by wiping with a damp cloth using a solvent-free cleaning agent (e.g. tenside).



Multiple use of the sterile disposable items as system accessories is excluded. 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 observed.

WARRANTY

The INJEX30 system has been carefully manufactured and in 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
info@injex.de

11. Troubleshooting

The reusable system components 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 5858382-63 (please keep the serial number when calling
e-mail: support@injex.de ready, which is located on the underside of the
injector is located)

problem	root cause	solution
Injector releases not from	The ampoule is not tight	Unscrew the ampoule firmly on the injector
	Ampoule not filled	Fill the ampoule
	No ampoule screwed on	Screw on the ampoule
	Circlip is in "safe" position	Circlip in "safe off" Slide position
Injector can not in the box insert	<i>Injector not secured</i>	Circlip in "safe" Slide position
	Injector or box heavily dirty	cleaning
	Injector in wrong position	Injector with trigger after top and open end in Insert in the direction of the hinge
Drug will not released	Ampoule opening blocked	Use a new ampoule
Reset box loads the Injector not	Injector or reset box strong dirty	cleaning
	Reset box not complete closed	Reset box completely shut down
	Injector already cocked	

12. Disposal

At the end of the useful life of the reusable system components, please dispose of them properly separately or return them to the manufacturer. The sterile disposable items (system accessories) must be disposed of 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 or 5000 trips

Injex ampoule

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) REF 338 011 0 0 2
+ Instructions for use, in the outer box:

Injector	1 piece	REF 338 010 0 0 1
INJEX ampoule U-100 / 0.3ml	50 pieces	REF 546 000 4 0 0
INJEX dosing aid adapter	20 piece	REF 511 000 7 0 0
INJEX pen adapter	20 piece	REF 511 000 5 0 0
INJEX bottle adapter-14	20 piece	REF 511 000 4 0 0
INJEX bottle adapter-22	20 piece	REF 511 000 8 0 0
INJEX Luer adapter	20 piece	REF 511 000 6 0 0
INJEX SiliTop	50 pieces	REF 516 000 0 0 0
INJEX dosing aid	1 piece	REF 338 012 0 0 0
INJEX reset box	1 piece	REF 338 013 0 0 0

15. Explanation of symbols



Warning!

For US Rx only

Under US federal law, this may
Device only on behalf of the treating
the Doctor in traffic / for use
can be brought.



One-time product, no
use several times



don't use if
damaged package



Sterilization by irradiation



Lot marking



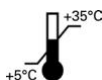
serial number



Reference number



Keep away from
moisture



Temperature limit



expiry date



Caution, instructions for use

look at instruction



Reference to the name of the
manufacturer

T h e S o f t S h o t

CE0297

SRN: DE-MF-000006766

Version number:

R06_2021_LAN



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