Injex Needle-free injection system

Information about the product
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Information for medical professionals

Fear of needle injections is widespread and the associated problems are numerous: crying children, long treatments, necessary therapies not or incorrectly applied.
This frequently results in serious secondary diseases that not only stress the patient but all of the associated aspects such as insurance companies and medication budgets.

RÖSCH AG Medizintechnik has developed an attractive alternative: INJEX™. The injection without needle

INJEX™ allows for easy subcutaneous injections.

Injex was initially developed especially for needle-free injection of Insulin. Further research & development have increased the number of applications, f.e. Dental Application; Local Anaesthesia, Homeosiniatry / Dupuytren Treatment, Human Growth Treatment, Erectile Dysfunction Treatment, Vaccinations.

The benefits at a glance:
-Injection without needle
-Virtually painless
-Veritably tissue preserving
-Strictly subcutaneous injection
-Fast, easy and safe in use and effect
-Individual dosing of medications
-No risk of infection as a result of needle-stick injuries
-Reduces fear as a result virtually painfree injection without needle
-Compact and can be used everywhere
-Economical
-Can be prescribed as medical aid (in Germany)
-Relieves physicians' medication budget (in Germany)

Injex basic components :
Basically, to perform an injection,
you need an Injex Ampoule and the Injector as you can see on the image below:

The Ampoule is filled with the medication and attached to the Injector.

The other components listed below are used to transfer the medication into an Ampoule, so you only have to choose the correct Adapter only once.

Development and Production of INJEX™

INJEX™ was developed and made available to the European market by RÖSCH AG Medizintechnik i.G..
Several patents have been issued for the INJEX™-system.
INJEX™ has market clearance and received European CE-approval (CE 0482) for pharmaceuticals suitable for subcutaneous jet-injection.
All conditions for cost reimbursement by health insurance companies according to § 139 Article 2 SGB V (German Code of Social Law, Volume 5) have been fulfilled since May 2002.
Starting immediately, INJEX™ - together with the consumables - can be prescribed and the respective health insurance
can use the assigned medical aid number (No. 03.99.10.0001) to reimburse costs.

CE Certification

INJEX™ is CE certified (CE 0482) within the European Union for the subcutaneous administration of medication suitable for jet injection.
Since September 1999, INJEX produced in Germany and categorised as an II B product according to the medical product law has been certified.
The first field of application was the use of U-100 insulin for diabetics.
By now, the areas of application for INJEX™ has been expanded greatly.
Rösch AG Medizintechnik strives to expand the use of INJEX™ to cover as many fields of application as possible.

Diabetes

The only available methods of administering insulin up to now have been subcutaneous injection with a traditional syringe or the use of an insulin pump. Most diabetics need several injections a day,
something considered highly unpleasant by the vast majority of diabetics.
In addition to the anxiety created by having to "stick oneself,"
many patients are afraid of annoying and cosmetically undesirable skin changes due to the repeated tissue damage by the needle.
Handling used and perhaps contaminated needles adds to the anxiety, especially if children are involved and the risk of injury and infection is thus higher as well.

The needle-free injections system INJEX offers a solution to this problem especially if feelings of unease and even outright fear of the traditional needle syringe prevent patients from starting a much-needed insulin therapy.
Injecting with INJEX is virtually pain free, gentle to the tissue, strictly subcutaneously, and safe.
Especially Type 2 diabetics frequently are not switched early enough from oral antidiabetica to insulin therapy although an early switch and controlling one's blood glucose prevents or delays secondary complications as shown by corresponding studies, e.g., in Great Britain.

RÖSCH AG Medizintechnik has discussed with experts the topic
„Zukunft der Diabetiker: Umstellung auf Insulin erleichtern - Kosten sparen."
(The Future for Diabetics: Facilitating Switching to Insulin - Saving Costs.)
The results of this discussion specialists are listed here: Monitor Kirchheim

Any aid contributing to the early switch to an insulin therapy, such as INJEX, for example, is a necessary and useful tool.
INJEX, together with the consumables, can be prescribed in Germany and the respective health insurance can reimburse costs.

How Injex works :

INJEX™ is a spring-loaded needle-less hypodermic injection system.

Jet injection propels a fine stream of liquid medication under high pressure through a small orifice through the skin.

All without a needle.

A Reset Box will cock the integrated spring before each use.
Sterile adapters enable the transfer of the desired medication from its vial into the disposable ampule for injection.
Once the required amount of medication has been transferred into the ampule, it is attached to the injector.

A reusable Dosage-Aid is available to draw up liquid drugs from cartridges (e.g. Insulin).
Once the required amount of medication has been transferred into the ampule, it is attached to the injector.
The injector is placed perpendicular to the desinfected injection site.

The INJEXION is released by pressing the trigger.
The high velocity jet stream pierces the skin and the drug disperses into the subcutaneous adipose tissue.
The injection is accomplished, the ampule is removed and discarded without special handling procedures associated with high disposal costs.

Which components do I need for an injection ?

Basically, to perform an injection,
you need an **Injex Ampoule** and the **Injex Injector**
as you can see on the image below:

The Ampoule is filled with the medication and attached to the Injector.

The other components listed below are mainly used to transfer the medication into an Ampoule, so you only have to choose the correct **Adapter** only once.

Example : if your medication is in a vial

SiliTop is a cap that can be placed on top of an Ampoule to further reduce pressure sensations / sensitive areas, for example Dental application / local anaesthesia

Overview of the available components of the Injex Needle-free injection system :

The INJEX **Injector** is the size of a ballpoint pen, lightweight (approx. 75g) and reusable.
A spring integrated into the injector produces the required energy to apply the medication in the subcutaneous fatty tissue. An Ampoule filled with the medication is screwed into the injector.

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The **Reset-Box** (reusable) is used for storing the injector. When the reset box is closed, a lever mechanism compresses the spring in the injector for recharging. So each time you open the Reset-Box, the Injector is ready to be used.

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The sterile- packed plastic **Ampoules** are single- use disposables and medical repositories.
During the injection process the movable plunger in the Ampoule forces the medical liquid through a micro orifice in the tip of the Ampoule at high speed, thus producing a high pressure liquid jet, which penetrates the skin.

In regard to the different uses, two versions of the Ampoule are available: 0,3 ml and 0,3 ml U100 (f.e. Insulin) The Ampoules are manufactured using the high-tech plastic Makrolon® from Bayer. In contrast to glass, Makrolon® is safe against breakage and fragmentation. A further strength of Makrolon® is: The user can exactly follow and control if the injection is complete and how many doses of medication she/he needs to fill. The recyclable high-tech plastic Makrolon® allows a disposal of the Ampoule as normal domestic waste. Please visit www.makrolon.de for further information about Makrolon®. The INJEX Ampoule is provided in a sterile package and designed to be used only once.

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Dosage Aid / Dosage-Aid-Adapter

The reusable **Dosage-Aid** is a dosing tool designed for transferring liquid medication from cylinder cartridges into the INJEX Ampoules with the **Dosage-Aid-Adapter**.
After inserting the cylinder cartridge, the adapter is screwed onto the Dosage-Aid for transferring the medication.
Subsequently, the Ampoule is screwed into the open end of Dosage-Aid adapter.

The **Dosage-Aid-Adapter** is a sterile disposable product designed for transferring medications from cylinder cartridges to the Ampoules.
It is used for connecting Dosage-Aid and Ampoule.
Once the contents of the cartridge have been used up, the cartridge and the adapter are disposed of.

Dosage-Aid + **Dosage-Aid Adapter** to fill the Ampoule with medication

Vial Adapter

The sterile **Vial Adapter** enables the transfer of pharmaceutical liquids from vials into the Ampoule.
The vial adapter is pressed firmly onto the head of the vial.
Now the ampoule can be screwed into the vial adapter.
Once the contents of the vial have been used up, the vial adapter and the vial are disposed of.

Vial Adapter on medication vial to fill the Ampoule with medication

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The **Pen Adapter** can be used to transfer insulin directly from the pen into the Ampoule
and matches with most of the available pens.
It is screwed on the pen instead of the needle.
Once the contents of the vial have been used up, the Pen adapter is disposed of.

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The **Luer Adapter** and a cannula with Luer-lock enable to fill the Ampoules with liquid medications
from all commercially available containers (e.g., snap-off Ampoules, vials).
Once the contents of the vial have been used up, the vial adapter and the vial are disposed of.

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SiliTop is placed on the tip of the Ampoule and reduces pressure sensations when the Injection is released.
SiliTop is a cap, especially developed for the dental application.
SiliTop is sterile packed and is a single-use disposable.

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Injex Dental

For decades ways have been sought for using local anaesthetic without the use of the needle. By now you can offer your patient -even children– a virtually painless and safe local anaesthetic with INJEX. Under use of pressure the local anaesthetic is applied under the mucosa with INJEX. As a result the penetration of the fluid into the deeper layers is achieving an adequate anaesthetic effect.

The benefits at a glance:

*Reduction for psychological barriers and anxieties because of virtually painfree application
*Easy and safe to use
*Timesaving because of faster onset of anaesthesia resulting from shorter dispersion period compared to the syringe
*Reduction in the risk of side effects as a result of lower dose
*Strictly localised effect, no undesired conduction anaesthesia
*Easy administration of the anaesthetic in comparison to a syringe (usually 0.3 ml are injected)
*Economical to use as smaller quantities of anaesthetic are required
*Injection-related stress kept to a minimum
*No risk of infection as a result of needle-stick injuries

INJEX: Easy and safe to use.

Local Anaesthesia

The needle-free injection system INJEX is already being used in many hospitals for local anaesthesia.
Extremely sensitive parts of the body such as hands, fingers,
elbows or head area can now be anaesthetised easily and nearly without pain.
After injecting with INJEX, a sufficiently deep analgesia takes effect rapidly.
The subsequent treatment of cuts or providing peripheral venous access is thus much more pleasant for the patient resulting in considerably less pain.

INJEX. The soft way to inject.

The Injex Needle free injection system is available from the **Online Shop**
or email us at: injex@heysterum.com

Local Anaesthesia / Dental Application / Information for Physicians

Local anaesthesia / Information for physicians

With the needle-free injector xylocaine or bupivicaine,
or its isomers can be administered subcutaneous for field,
ring or sensory nerve block anaesthesia. In the conducted study with eight patients,
all injection doses used were 0.3 cc of 0.5 % bupivicaine.

"Extremely sensitive parts of the body such as hands, fingers, elbows or head area can now be anaesthetised with INJEX easily and virtually painless."
In outpatient clinical settings, INJEX offers many advantages over the subcutaneous infiltration of
local anaesthetics via needle whether used with or without Fluorimethane spray.
Please read the study: A preliminary study using INJEX with local anaesthesia

Makrolon

Bayer MaterialScience

Makrolon® - a plastic with feeling
Safe and breakproof: Ampoules made of Makrolon®

Injections at home
In the family home, the atmosphere has become much more relaxed now that the unpleasant procedure of
giving a member of the family the regular thrombosis injection has been made so much easier.
The anxiety and apprehension associated with the needle are now consigned to the past,
both for the patient and for the people nursing him.
With the aid of a needle-free injection, the medication can now be inserted beneath the skin without any actual pinprick.
The INJEX™ injection system uses Ampoules made of Makrolon®.
For good reason, because Makrolon® is breakproof,
does not splinter and is the material of choice whenever optimum quality is called for.

Injections without needles
The era of the unpleasant pinprick is over.
Insulin jabs for diabetics, growth hormones for children,
Anti-thrombosis agents at home: with the Injex system,
the liquid medications are filled into the sterile Makrolon® Ampoules.
The medication is then forced at high pressure through a micro orifice in the Ampoule and into the fatty tissue under the skin almost painlessly.
And that makes life a lot easier for patients who need regular injections.

Safety in medical technology
Makrolon® easily resists the pressure and the mechanical loads applied during the injection.
Because the high-tech plastic is transparent,
the patient can see how much medication is left in the Ampoule and whether the injection was complete.
In medical technology, Makrolon® has become indispensable.
For example, this high-tech material has also played a major role in dialysis becoming a simple everyday procedure for kidney patients.

Other applications

The list of other fields of application for Injex Needle-free continues to grow :

- Diabetes
- Dental Application
- Local Anaesthesia
- Homeosiniatry
- Dupuytren Treatment,
- Human Growth Hormone Treatment
- Erectile Dysfunction Treatment
- Vaccinations
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