PAJUNK®

SonoMSK

Pain Management

Instructions for use

These instructions for use were translated into the following languages: DE, EN, FR, IT, ES, PT, NL, DA, SV, EL, BG, ET, HR, LV, LT, PL, RO, SK, SL, CS, HU. The translations can be downloaded from our website: eifu.pajunk.com.

Special notice

Please read the following information and operating instructions carefully.

Caution: Federal law restricts this device to sale by or on the order of a physician. The device may only be used by qualified medical staff in accordance with these user instructions.

PAJUNK® does not recommend any particular treatment method. Professional medical staff are responsible for the way in which the device is used and for patient selection.
In addition to these instruction for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.
Failure to comply with the instructions for use invalidates the warranty and puts patient safety at risk.
If used in combination with other devices, it is essential that the compatibility information and user instructions for these other devices are taken into account. A decision regarding the combined use of devices from different manufacturers (where they do not constitute treatment units) is the responsibility of the user.

The device must not be used under any circumstances if there are good reasons to suspect incompleteness, damage or loss of sterility.

Only devices in perfect condition, which are within the sterile expiry date marked on the label, in undamaged packaging, may be used.

Device description/compatibility

Please see the current declaration of conformity for product numbers and the scope of these instructions for use.

SonoMSK with Cornerstone reflectors, bevelled grinding, depth graduation, with mounted injection tube

Hub connectivity: LUER

Intended use

Puncture, aspiration and injection in muscles, joints, tendons and ligaments.

PAJUNK® cannulas can also be introduced into the body under ultrasound, fluoroscopic or CT guidance.

Warning:
The cannula is not suitable for MRI use!

Target user group

Medical specialist staff only; orthopedists, rheumatologists, radiologists, sport physicians, physiatrists, primary care physicians.

Target patient population

Adults and children.

Indications

Musculoskeletal aspiration and injection

Contraindications

Device-specific contraindications

Under no circumstances is the device to be used in the event of known material incompatibilities and/ or known interactions.

Contraindications to musculoskeletal injection
Hypersensitivity to injectable substance, uncontrolled coagulopathy, intra-articular fracture, infection (local or systemic infection, overlying cellulitis, septic arthritis/ bursitis, osteomyelitis), tendinous sites with high risk of rupture, broken skin at site of injection, prosthetic or unstable joint, necrosis, bacteremia.

Complications

Device-specific complications

Inaccurate cannula placement, cannula bending/ breakage, cannula occlusion, leakage at hub.

Clinical complications

Vascular injury, pain, bleeding, infection, septic arthritis, drug allergy, hematoma, pneumothorax.

Drug related complications

Tendon rupture, soft tissue atrophy, arthropathy, osteonecrosis, hyperglycemia, hypopigmentation, post-injection flare, fascial flushing, menstrual irregularity, increased pain after therapy.

Users must inform patients of complications typically associated with the procedure.

If complications occur while using the device, follow the protocols of your organisation. If this does not resolve the complications, or if they are regarded as serious or untreatable, carefully stop the procedure and remove invasive device components from the patient.

Warnings

⚠ *for sterile product:*

This is a disposable medical device for use with only one patient!

This device must not be re-used under any circumstances!

This device must not be resterilised under any circumstances!

The materials used in the manufacture of this device are not suitable for reprocessing or resterilisation.
This device is not designed to be reprocessed or resterilised.

⚠ Unauthorised re-use or reprocessing

- can cause the device to lose the essential performance properties intended by the manufacturer.
- leads to a significant risk of cross-infection/ contamination as a result of potentially inadequate processing methods.
- may cause the device to lose functional properties.
- may cause materials to break down and lead to endotoxic reactions caused by the residues.

⚠ *for puncture:*

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. After having positioned the cannula, check by aspiration whether the position is correct. If you notice blood in the injection tube or the syringe, cancel the procedure.
3. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
4. In case of unexpected bone contact, withdraw the cannula and change its direction.
5. Repeated bone contact will damage the cannula tip. On no account you should continue to use a cannula damaged in this manner. In case of a previous bone contact remove the cannula in one step.

⚠ *for injection:*

1. Always ensure that the injection site is aseptic.
2. Do not administer drugs that are not indicated for the intended use.
3. Be sure to regularly check the connection between the cannula and the infusion device.

⚠ *for use with other compatible products:*

When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).

further warning indications:

1. Caution: Sharp object warning. The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. For practical purposes, the most important of these are the human immunodeficiency virus (HIV), the hepatitis B virus (HBV) and the hepatitis C virus (HCV).
2. You must routinely take general precautions for handling blood and bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.
3. Please note that the continued use of a device of the same type must be assessed cumulatively as described in the legislation on medical devices, even after the device has been exchanged or replaced.

Sequence of use

1. Disinfect the skin and cover the puncture area with a sterile fenestrated drape (optional: perform local anaesthesia).
2. Advance the cannula through the skin.
3. Placement of the cannula.
4. Check its correct position by means of aspiration, if required.
5. Continue procedure in accordance with the individual indication.

Use and storage conditions

	Temperature limit	+10 °C to +30 °C
	Humidity limitation	20 % to 65 %
	Keep away from sunlight	
	Keep dry	

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

Any serious incident that has occurred while using the device should be reported to the manufacturer and the corresponding authorities of the country the user and/or patient are residing in.

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling


Manufacturer


Use-by date

Item number

Sterilized using ethylene oxide

Do not resterilize


Do not use if package is damaged


Keep dry


Humidity limitation


Do not re-use


Caution


Date of manufacture

Batch code


Keep away from sunlight


Temperature limit


Consult instructions for use


Single sterile barrier system

Dispensing with prescription only (the device may only be used by qualified medical staff for the intended purpose.)

MR unsafe


Advice


Information

"CE conformity marking" or "CE marking" = this marking shows that a device is in conformity with the applicable requirements as set out in the Medical Device Regulation or other European Union legislation on its affixing.


Sharp object warning

Does not contain phthalates

Does not contain natural rubber latex

Quantity


Translation

Medical device

Unique device identification


Single sterile barrier system with protective packaging outside

CE 0124

XS190314C_Englisch 2023-04-20

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