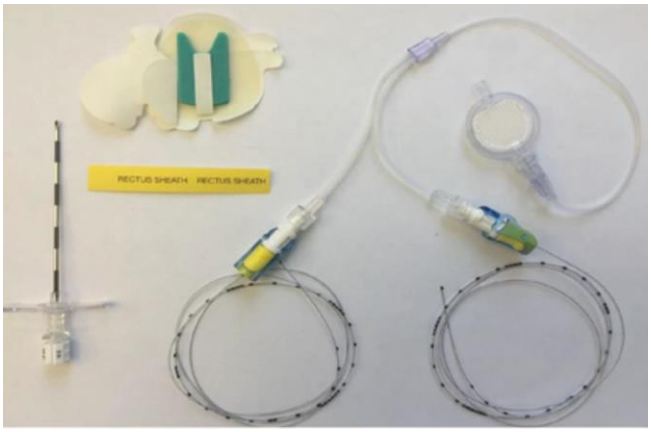
Technical Specification Datasheet –
Customer Certification of the finished Device

	Manufacturer: **PAJUNK® GmbH Medizintechnologie** Karl-Hall-Strasse 1 78187 Geisingen Germany	Distributor: *[Authorized Stamp here]*
	Manufactured according to ISO13485, ISO14971, GMP	
	The product and manufacturing process is free of Latex.	
	Project	R20-0416
	Device	**Peripheral Nerve Block Kit**: Pre-assembled customized procedure kit; Needle/ Cannula: Tuohy, facet; Injection tube; Infiltration Catheter; NRFit
		Trade name: Rectus Sheath NRFit Generic name: Peripheral anaesthesia catheter set, non-medicated
	Custom-made	No
	Regulatory Information	Regulation 2017/745 (MDR) class IIb, rule 7-6 GMDN: 46383 Peripheral anaesthesia catheter set, non-medicated
	Basic-UDI-DI	4048223-R20-0416D6
	EC Certificate	51268-60-04
	Notified Body	DEKRA Certification GmbH, Stuttgart; NBC: 0124
	Item codes	Please refer to the corresponding Declaration of Conformity R20-0416

	Device Description	The RECTUS SHEATH NRFit kit subject to this file is pre-assembled customized procedure kit. It is a sterile, single use product The kit contains the following components: • Tuohy, Cannula/ needle • Catheter • Retaining plate/ "wings" • Insertion Aid NRFit • ClampingAdapter NRFit • Y-tube • Filter: bacterial filter • Locking cap NRFit • FixoLong • FixoCath
	Intended Use	Puncture, access to the target area, aspiration, injection, catheter placement. The catheters are intended to remain in the target area and constantly deliver local anaesthetic emitted by an external source
	Patient population	Not restricted
	Procedure	*Placement of the cannula* 1. Perform skin disinfection and cover puncture area with a sterile fenestrated surgical drape (aperture drape), local anesthesia. 2. Perforating incision (lancet etc.) 3. Advancement of the cannula under the skin. 4. Determination of the position of the cannula. 5. Anaesthetic may be administered as soon as the exact localization and the fixation of the cannula has been completed. *Catheter placement* 1. Put the introductory aid on the cannula hub. 2. Push the catheter with the marked end up to the required depth into the target area. 3. After successful positioning, remove the cannula over the catheter. Hold the catheter tightly with the other hand, if necessary. 4. After removing the cannula, connect the catheter to the clamping adapter. 5. Fill the filter with the anesthetic solution designated to be used at the beginning of the anesthesia / analgesia to compensate for the dead volume (the filling volume of the filter is approximately 0.8 ml). 6. Connect the catheter adapter to the hub of the filter.

		7. Fill a 10 ml or 20 ml syringe with the selected anesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection. 8. Fasten the catheter with the optionally available FixoLong or FixoCath in the vicinity of the exit point.. <u>Fastening of the FixoLong (optional):</u> 1. The PAJUNK® adhesive bandage with the fixated catheter cross is fastened in the vicinity of the catheter exit. 2. The catheter is snapped onto the fastening clips. This guarantees maximum freedom of movement while simultaneously fixating the catheter. 3. The filter adapter is plugged onto the catheter cross. 4. Secure the flat filter on the filter adapter.
	Picture (not for scale)	
	Compatibility	The catheter is compatible to the cannula, which have the corresponding diameter. Compatibility of the devices/ kit components is given by using standardized interface according to ISO 80369-6: NRFit

	Materials	Cannula tube: Stainless Steel Cannula hub: Tritan Catheter: Polyamide, stainless steel (helical coil) Injection tube: PVC NoDoP (contains TOTM); Polycarbonate Filter: Media: Polyethersulfone membrane Housing: Modified acrylic Clamping Adapter: Polycarbonate, SRT FixoLong: Filter retainer: Polycarbonate catheter cross: Polycarbonate gluing pad: coating: medical gluing pad: Polyethylen foam safety foil: siliconised paper FixoCath: 1. Backing paper: Paper + PE coated with Lina silicone system 8500 2. Primary carrier: Hydrocolloid and polyurethane film 3. Support cushion: Polyethylene foam with adhesive 4. Adhesive for catheter friction: Acrylic adhesive with PVC carrier 5. Siliconized paper protection: Paper + PE coated with Lina silicone system 8500 6. Non-woven/ hydrocolloid lid: White non-woven Sontara with acrylic adhesive combined with hydrocolloid LockingCap: MABS polymer	
	Packaging	**Single device:**	Hardblister: GGG PET / tyvek Heat sealed
		Multiple Units:	card board box
	Additional information		Non-pyrogenic
			Does not contain latex
			Does not contain Phthalates
☒	Biocompatibility	Proven biocompatibility according to FDA modified ISO10993-1: (short-term, invasive patient contact) for all relevant parts.	

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USt-IdNr.: DE 812493272
Sitz der Gesellschaft: Geisingen
Registergericht: Stuttgart HRB 450245
Geschäftsführung:
Simone Pajunk-Schelling, Martin Hauger

Bank:
Volksbank eG Villingen IBAN: DE14 6949 0000 0080 0577 09 | BIC: GENODE61VS1
Deutsche Bank Villingen-Schwenningen IBAN: DE72 6928 0035 0832 9333 00 | BIC: DEUTDE6F694
Commerzbank AG IBAN: DE72 6928 0035 0832 9333 00 | BIC: DRESDEFF692

☒	Sterility	STERILE EO	SAL 10^{-6}, validated process, regular tests per product Sterilized with: ☒ EtO ☐ Gamma
☒	Shelflife (sterility and performance)		60 month from manufacturing, Label imprint. 5 years
☒	Further Imprints		Indicates Date of Manufacturing
		LOT	Indicates Lot - by consecutive numbering per sterile batch
☐	Re-Sterilization	Not applicable	
☐	Maintenance	Not applicable	
☒	Special Attention		Carefully read Instructions for use!
			Do not use if product or packaging is damaged
			Keep away from sunlight
			Keep away from rain
			Disposable! Do not re-sterilize! Re-use may harm patient!
			Disposable! Do not re-use! Re-use may harm patient!
			Storage: Temperature Range 20 ±10 °C
			Storage: Humidity Range 20-65%

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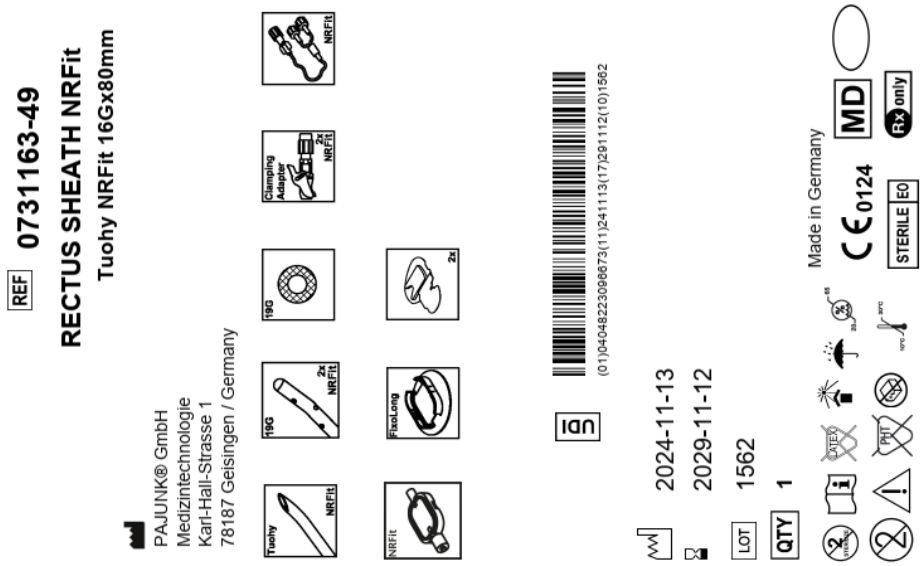
	Label sample/ Marking patterns	Individual: 
	Label sample/ Marking patterns	Box: 
WARNING! **For all obese patients select appropriate and corresponding dimensions (diameter and length) of the cannula.**		
Released/Update	February 18th 2026	

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