

Needle Guides

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Product Name: Needle Guides:

- Needle Guide Aloka UST-945B-5, UST-952-5 series, UST-977-5, UST-981-5, UST-984-5 & UST 9112-5
- Needle Guide Aloka UST9118 & UST9124
- Needle Guide Samsung Medison EA2-11B, Siemens EC9-4 & EV9-4
- Needle Guide Siemens EC7, EC9-4 & EC10C5
- Needle Guide Esoate EC1123, IVT12, SE3133 & TRT12, GE IC5-9W-RS, Philips E6509, PIE C7-4R8 TRD, Siemens BE9-4, Samsung Medison BCC4-9 & Terason 8EC4A
- Needle Guide Siemens Endo V
- Needle Guide ECM E610P, GE E72, E721, E8C, E8C-RS, E8CS, IC5-9D, IC5-9H, MTZ & MZ
- Needle Guide GE RIC5-9-D, RIC5-9A-RS, RIC5-9W-RS & RIC6-12-D
- Needle Guide Hitachi EUP-CC331, EUP-V33, EUP-V33W, EUP-V12, EUP-V53, EZU-PA5V & Sonoscape 6v3
- Needle Guide Aloka UST-679, BK Medical E10C4, Philips BPI0-5ec & C9-4ec, Samsung Medison ECM E610R, ER4-9/10ED, EV4-9/10ED, NER4-9ES, NEV4-9ES & Ultrasonix EC9-5
- Needle Guide Philips C8-4v & C9-3v
- Needle Guide Siemens EC9-4 (ACUSON S1000, S2000, S3000, SONOLINE Antares™), Toshiba PVF-641VT, PVG-601V, PVG-630V, PVM-651VT, PVN-661VT, PVQ-641V & PVT-661VT
- Needle Guide Toshiba PVM 740RT & PVT 770RT

Product Codes: R57525-00-AK, R57525-00-AL, R57525-00-EC, R57525-00-ED, R57525-00-ES, R57525-00-EV, R57525-00-GE, R57525-00-GS, R57525-00-H, R57525-00-ME, R57525-00-PI, R57525-00-T, R57525-00-T3

Device Image (Example):



R57525-00-AK: Needle Guide Aloka UST-945-5, UST-945B-5, UST-952-5 series, UST-977-5, UST-981-5, UST-984-5, UST 9112-5

Intended Use: Intended for attachment to specified ultrasound transducers to provide a means of support for an oocyte retrieval needle during transvaginal, ultrasound-guided oocyte harvesting procedures.

Indications: For use in transvaginal, ultrasound-guided oocyte harvesting procedures.

Contraindications: These devices are contraindicated for use in patients

- with suspected or confirmed pregnancy, as the procedure may cause miscarriage or fetal injury
- where the pelvic anatomy cannot be accurately assessed by ultrasonography, as the procedure may cause damage to other organs or blood vessels.
- with vaginal or sexually transmitted infections, as this may increase the severity of the infection.

Benefit Risk: Rocket Medical plc has taken all necessary steps to ensure that residual risks associated with the use of Needle Guides are reduced as far as possible through application of existing state of the art techniques in the design and manufacture of these medical devices to ensure safe usage. Rocket Medical plc concludes that the overall medical benefits of Needle Guides, outweigh the possible risks when used according to the intended use.

Performance Claims and Clinical Benefit:

The intended performance claims for needle guides are:

- Attaches to the endocavity transducer probe
- Provides a channel to support the needle during oocyte retrieval procedures

The intended clinical benefit is to assist with the harvesting of oocytes for use in ART procedures.

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

Description of the device: The Needle Guides are intended for the attachment of needles to specified ultrasound transducers for use in transvaginal ultrasound guided oocyte harvesting procedures. There are many variations which vary in shape in order to allow secure attachment to the specified ultrasound transducers. Each needle guide is moulded using an Acrylonitrile Butadiene Styrene (ABS) copolymer with a stainless-steel tube inserted through the centre to allow the needle clear passage.

User: The intended user is a healthcare professional proficient in the undertaking of oocyte retrieval, working in accordance with local and national guidelines, or a trainee under the supervision of such a person.

Patient Population: The intended patient demographic is patients of child-bearing age undergoing oocyte retrieval.

Environment: Clinical setting with close access to sharps and clinical waste bin

For Single Use Only: The device may not have structural integrity to support reuse, resulting in harm to the patient and/or user. Re-use may result in harm to patients and users from cross-contamination and infection.

Sterile: The devices are supplied sterile by Ethylene Oxide (EO). Do not re-sterilise; it may not be possible to achieve the required sterility assurance level upon re-sterilisation of a used device. Re-sterilisation may also compromise the structural integrity of the device, leading to device failure.

MRI Safety: This device is not intended to be routinely found in an MRI environment and compatibility has not been verified.

General Information:














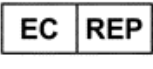



Reference Code	Device Name	Compatible Transducers	Ultrasound	Accepts Needle Size of:
R57525-00-AK	Needle Guide Aloka UST-945-5, UST-945B-5, UST-952-5 series, UST-977-5, UST-981-5, UST-984-5, UST 9112-5	Aloka UST-945-5 Aloka UST-945B-5 Aloka UST-952-5 series Aloka UST-977-5 Aloka UST-981-5 Aloka UST-984-5 Aloka UST 9112-5		15-18G
R57525-00-AL	Needle Guide Aloka UST9118 & UST9124	Aloka UST-9118 Aloka UST-9124		15-18G
R57525-00-EC	Needle Guide Samsung Medison EA2-11B, Siemens EC9-4 & EV9-4	Samsung Medison EA2-11B Siemens EC9-4 Siemens EV9-4		15-18G
R57525-00-ED	Needle Guide Siemens EC7, EC9-4 & EC10C5	Siemens EC7 Siemens EC9-4 Siemens EC10-C5		15-18G
R57525-00-ES	Needle Guide Esoate EC1123, IVT12, SE3133 & TRT12, GE IC5-9W-RS, Philips E6509, PIE C7-4R8 TRD, Siemens BE9-4, Samsung Medison BCC4-9 & Terason 8EC4A	Esoate EC1123 Esoate IVT12 Esoate SE3133 Esoate TRT12 GE IC5-9W-RS Philips E6509 PIE C7-4R8 TRD Siemens BE9-4 Samsung Medison BCC4-9 Terason 8EC4		15-18G
R57525-00-EV	Needle Guide Siemens Endo V	Siemens Endo-V		16-18G

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

R57525-00-GE	Needle Guide ECM E610P, GE E72, E72I, E8C, E8C-RS, E8CS, IC5-9D, IC5-9H, MTZ & MZ	ECM E610P GE E72 GE E72I GE E8C GE E8C-RS GE E8CS GE IC5-9-D GE IC5-9H GE MTZ GE MZ	16-18G
R57525-00-GS	Needle Guide GE RIC5-9-D, RIC5-9A-RS, RIC5-9W-RS & RIC6-12-D	GE RIC5-9-D GE RIC5-9A-RS GE RIC5-9W-RS GE RIC6-12-D	15-18G
R57525-00-H	Needle Guide Hitachi EUP-CC33I, EUP-V33, EUP-V33W, EUP-V12, EUP-V53 & EZU-PA5V, & Sonoscape 6v3	Hitachi EUP-CC33I Hitachi EUP-V33 Hitachi EUP-V33W Hitachi EUP-V12 Hitachi EUP-V53 Hitachi EZU-PA5V Sonoscape 6v3	15-18G
R57525-00-ME	Needle Guide Aloka UST-679, BK Medical E10C4, Philips BP10-5ec & C9-4ec, Samsung Medison ECM E610R, ER4-9/10ED, EV4-9/10ED, NER4-9ES, NEV4-9ES & Ultrasonix EC9-5	Aloka UST-679 BK Medical E10C4 Philips BP10-5ec Philips C9-4ec Samsung Medison ECM E610R Samsung Medison ER4-9/10ED Samsung Medison EV4-9/10ED Samsung Medison NER4-9ES Samsung Medison NEV4-9ES Ultrasonix EC9-5	15-18G
R57525-00-PI	Needle Guide Philips C8-4v & C9-3v	Philips C8-4v Philips C9-3v	15-18G
R57525-00-T	Needle Guide Siemens EC9-4 (ACUSON S1000, S2000, S3000, SONOLINE Antares™), Toshiba PVF-641VT, PVG-601V, PVG-630V, PVM-651VT, PVN-661VT, PVQ-641V & PVT-661VT	Siemens EC9-4 (ACUSON S1000, S2000, S3000, SONOLINE Antares™) Toshiba PVF-641VT Toshiba PVG-601V Toshiba PVG-630V Toshiba PVM-651VT Toshiba PVN-661VT Toshiba PVQ-641V Toshiba PVT-661VT	15-18G
R57525-00-T3	Needle Guide Toshiba PVM 740RT & PVT 770RT	Toshiba PVM-740RT Toshiba PVT-770RT	15-18G

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

Symbols and safety signs used on the device and labelling:

Symbol or Safety Sign	Meaning	Symbol or Safety Sign	Meaning
	Manufacturer		Keep away from sunlight
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Do not re-use
	Date of manufacture		Consult the instructions for use
	Use-by date		Does not contain natural rubber latex
	Batch code		Medical device
	Catalogue number		Do not use if package is damaged and consult instructions for use
	Sterilized using ethylene oxide		Authorised Representative in the European Community
	Do not re-sterilise		Importer
	Distributor		

Operation and Mode of Action:

CHECK: Do not use if the packaging is open or damaged or the device is damaged.

CHECK: Before using the needle guide for the first time, verify that the needle guide that is compatible with the ultrasound transducer probe being used.

Ensure you have the following consumables and accessories available to perform the oocyte retrieval (the following are not provided with Rocket Medical Needle Guides): -

- Endocavity transducer
- Transducer sheath and gel
- Oocyte aspiration needle
- Oocyte collection vessel
- Oocyte aspiration pump
- Pump patient connection set

1. Using aseptic technique, use a protective sheath to cover the transducer. Follow the manufacturer's instructions for use to carry out this step.
2. Make sure there are no wrinkles or tears in the sheath and then secure this in place following the manufacturer's instructions for use.

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

3. Using aseptic technique, align the needle guide to the transducer. Press down on the needle guide and ensure it is securely connected. Check that this has not perforated the protective sheath.
4. Insert the aspiration needle into the needle guide.
5. Carry out the procedure.
6. Once the procedure is complete, remove the sheath and needle guide from the transducer probe.

Disposal: This device, its accessories and the consumables used with it, should be handled and disposed of in accordance with policy of the healthcare setting and with regard to all applicable regulations, including but without limitation to, those pertaining to human health and safety and care of the environment. Failure to do so may increase the risks of infection or other microbial hazards. Take care when handling sharps, to avoid needlestick injuries. Ensure sharps are disposed of in sharps containers.

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.