INSTRUCTIONS FOR USE

Vanguard Steerable Diagnostic Catheter SJA &
Vanguard Steerable Diagnostic Catheter SJF

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CE 0481

GENERAL

Read these instructions carefully before using the product described. If you have questions concerning the instructions for use or handling of the product, please contact our Customer Service Centre at service@vanguard.de or contact our field staff before using the product on patients.

General information

These instructions contain certain notations which are intended to help you understand the functions and meaning of the text more quickly:

- ✓ Requirements
- → Instructions
- • Lists
- ⚠ Safety instructions

The original version of these instructions for use is in German.

Device information

This product may only be operated if its safe use is guaranteed. Observe the notes on safety and usage!

VANGUARD AG assumes no liability for damages that arise from improper operation of the Vanguard Steerable Diagnostic Catheter SJA & SJF and/or disregard of these instructions for use.

Vanguard AG and the manufacturer of the original product, St. Jude Medical, Inc., USA, (The Corporate Village Building Figueras, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium) are not affiliated companies; the device is fully refurbished solely by Vanguard AG, who markets the device without collaboration by St. Jude Medical, Inc.
"St. Jude Medical" and "Inquiry" are protected brands of the manufacturer of the original product, St. Jude Medical, USA, or one of its affiliated companies.

Packaging labelling and symbols

Content:
one (1) Vanguard Steerable Diagnostic Catheter SJA or
one (1) Vanguard Steerable Diagnostic Catheter SJF

The medical device may only be used (⌛) until the specified "Expiry date”

	Do not reuse
	Do not resterilise
	Do NOT use if the sterile packaging is damaged or opened
STERILE EO	Sterile, sterilisation using ethylene oxide
⌛	Expiry date
SN	Serial number
	Store away from light
	Store in a dry place
	Information about acceptable ambient temperature during storage and transportation
	Follow the instructions for use
CE 0481	CE mark with identification number of the notified body
	Manufacturer
REF	Item number

PRODUCT DESCRIPTION

The Vanguard Steerable Diagnostic Catheter SJA and the Vanguard Steerable Diagnostic Catheter SJF consist of a torsion-resistant shaft and a steerable tip with several electrodes. This catheter is intended for temporary intracardiac recording of potentials and temporary stimulation of the heart during electrophysiological examinations.

The curvature of the tip is controlled by a movable plunger with a thumb switch in the hand piece at the proximal end of the catheter. To bend the tip, the thumb switch is pushed forward. When the thumb switch is in the rear position, the tip is straight. The tip curvature depends on the length of the steerable tip and the position of the thumb switch. Catheters are available with different tip curvatures. The designations of the curvatures correspond to the designations of the original manufacturer St. Jude Medical, Inc.: “M", “M/L”, "L", "XL", "XXL" and "SL".
An extension cable with an appropriate plug connector should be used to connect it to a suitable standard recording device.

Intended use

The Vanguard Steerable Diagnostic Catheter SJA and the Vanguard Steerable Diagnostic Catheter SJF are intended for temporary intracardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations. They are usually applied at the Bundle of His, in the high right atrium and in the right ventricular cardiac apex.
The catheter is not suitable for ablation.

It is the responsibility of the physician to use a suitable surgical procedure and technology. The procedure described in the instructions for use is for information purposes only. Each physician must apply, supplement or adapt the information in the instructions for use according to his/her medical training and clinical experience. The medical device may only be used by a trained and experienced specialist physician.

All Vanguard Steerable Diagnostic Catheter SJA & SJF are equally compatible with the accessories (e.g. generator, cables) as the corresponding products of the original manufacturer St. Jude Medical, Inc.

Technical data

Vanguard Steerable Diagnostic Catheter SJA

Usable length: 110 cm
Connection: 9-pin, 14-pin or 26-pin (Redel)

Item No.	original ref. no.[1]	Shaft diameter	Curve type	Electrodes			Connection (corresponds to St.Jude cable)
				Quantity	Width [mm]	Distance [mm]	
34417	IBI-81540	4F = 1.3 mm	M	4	1	2-5-2	9-pin (1904-S)
34418	IBI-81474	5F = 1.7 mm	L	4	1	2-5-2	9-pin (1904-S)
34419	IBI-81472	5F = 1.7 mm	M	4	1	2-5-2	9-pin (1904-S)
34420	IBI-81404	6F = 2.0 mm	L	4	2	2-5-2	9-pin (1904-S)
34421	IBI-81402	6F = 2.0 mm	M	4	2	2-5-2	9-pin (1904-S)
34422	IBI-81418	6F = 2.0 mm	XL	4	2	2-5-2	9-pin (1904-S)
34423	IBI-81405	6F = 2.0 mm	L	4	2	5	9-pin (1904-S)
34454	IBI-81403	6F = 2.0 mm	M	4	2	5	9-pin (1904-S)
34455	IBI-81809	6F = 2.0 mm	L	8	1	2-5-2	14-pin (1910-S)
34456	IBI-81802	6F = 2.0 mm	M	8	1	2-5-2	14-pin (1910-S)
34424	IBI-81807	6F = 2.0 mm	L	8	1	2	14-pin (1910-S)
34425	IBI-81801	6F = 2.0 mm	M	8	1	2	14-pin (1910-S)
34426	IBI-81532	4F = 1.3 mm	L	10	1	2-5-2	14-pin (1910-S)
34427	IBI-81531	4F = 1.3 mm	M	10	1	2-5-2	14-pin (1910-S)
34371	IBI-81530	4F = 1.3 mm	M	10	1	2	14-pin (1910-S)
34372	IBI-81174	5F = 1.7 mm	L	10	1	2-5-2	14-pin (1910-S)
34428	IBI-81172	5F = 1.7 mm	M	10	1	2-5-2	14-pin (1910-S)
34429	IBI-81104	6F = 2.0 mm	L	10	1	2-5-2	14-pin (1910-S)
34430	IBI-81102	6F = 2.0 mm	M	10	1	2-5-2	14-pin (1910-S)
34431	IBI-81105	6F = 2.0 mm	XL	10	1	2-5-2	14-pin (1910-S)
34432	IBI-81108	6F = 2.0 mm	L	10	1	2	14-pin (1910-S)
34370	IBI-81107	6F = 2.0 mm	L	10	1	5	14-pin (1910-S)
34433	IBI-81202	7F = 2.3 mm	XXL	20	1	2-10-2	26-pin (1924-S)
34434	IBI-81209	7F = 2.3 mm	SL	20	1	2-5-2	26-pin (1924-S)
34435	IBI-81207	7F = 2.3 mm	SL	20	1	5	26-pin (1924-S)

Other data → see label

[1] Corresponding REF. No. of the original manufacturer

Vanguard Steerable Diagnostic Catheter SJF

Usable length: 110 cm

Connection: 14-pin (Redel)

Item No.	original ref. no.[2]	Shaft diameter	Curve type	Electrodes			Connection (corresponds to St.Jude cable)
				Quantity	Width [mm]	Distance [mm]	
35091	81734	5F = 1.7 mm	L	10	1	2-5-2	14-pin (1910-S)
35092	81730	5F = 1.7 mm	M/L	10	1	2-8-2	14-pin (1910-S)
35093	81735	5F = 1.7 mm	L	10	1	5	14-pin (1910-S)
35094	81945	6F = 2.0 mm	L	10	1	2-5-2	14-pin (1910-S)
35095	81947	6F = 2.0 mm	M/L	10	1	5	14-pin (1910-S)

Other data → see label

"Redel" is a protected brand of INTERLEMO HOLDINGS S.A., Ecublens, CH or the brand of a manufacturer associated with this company.

The catheters are used in connection with compatible connection cables from the company St. Jude Medical, Inc. and suitable devices for electrophysiological mapping (recording of signals and stimulation).

St. Jude		Compatible connection cables
REF No.	Order no.	
1904-S*	85953	4-Pin Diagnostic Connection Cable 150cm
1910-S*	85930	10-Pin Diagnostic Connection Cable 150cm
1924-S*	85931	24-Pin Diagnostic Connection Cable 150cm

*S = shrouded pin

CE 0481

This product bears a CE mark in accordance with the requirements in the EC directive 93/42/EEC and all applicable changes.

[2] Corresponding REF. No. of the original manufacturer

SAFETY INSTRUCTIONS

The safety instructions consist of three aspects: Cause, Consequence, Countermeasure.
A safety instruction indicates a potential risk to the health or life of persons.

⚠ Proximal plug connection or handle comes into contact with liquid!

Interference with the function of the catheter

→ Prevent the connector from coming into contact with liquids.

⚠ Electrical contacts of the catheter or connected cables are electrically connected to the heart!

Ventricular fibrillation due to uncontrolled electrical energy

→ Do not touch the plug contacts of the catheter or of connected cables with your fingers or with objects.

→ Only connect the catheter's plug contacts to medical devices using connection cables which meet requirements and are intended for this purpose.

→ Do not allow the catheter's plug or the connection cable's plug to come into contact with liquids. This can impair the electrical safety and functionality.

⚠ Electromagnetic interference due to an external pacemaker!

Damage or interference of other devices, ventricular fibrillation and burns

→ Only use the catheter in a properly equipped and operated medical electrophysiology laboratory.

⚠ Plug connector damaged!

Interference with electrical safety and function

→ Carry out a careful visual inspection and functional inspection of the plug.

⚠ Transfer of electrostatic discharges to the catheter system!

Ventricular fibrillation due to uncontrolled electrical energy

→ Only use the catheter in a properly equipped and operated medical electrophysiology laboratory.

⚠ Long fluoroscopy times with X-rays!

Somatic and genetic damage due to high exposure to ionising radiation

→ Particularly for pregnant women, children, young patients and patients who have to undergo several examinations, reconsider the risk/benefit ratio as a consequence of the potential effects of radiation.

⚠ Sterilised package is damaged or opened!

Infection of the patient due to unsterile products

→ Check the packaging before opening it and, if necessary, do not use the catheter.

⚠ Damage due to improper handling and/or unsuitable storage conditions!

Damage to the central circulatory system, infection, septicaemia

→ Take note of the intended use and the relevant identification on the packaging.

→ Do not expose the catheter to any organic solvents such as alcohol.

⚠ Improper catheter use or the thumb switch not pushed back!

Injuries, perforations and tamponades in the heart and vascular system

→ Ensure that only trained personnel uses the catheter.

→ Always push the thumb switch backwards to insert or remove the catheter in order to put the catheter tip into a straight position.

→ If there is resistance, do not use force to push the catheter forwards or backwards.

⚠ Reprocessing, including resterilisation and reuse of the catheter by the user or operator!

Injury of blood vessels and intracardiac injuries, infection, septicaemia

⟶ Ensure that the catheter is not reprocessed, resterilised or reused.

HANDLING INSTRUCTIONS

The catheter must be handled with great care in order to avoid injuries, perforations and tamponades in the heart and vascular system.

Storage

→ Information about storage conditions is given on the label on the product packaging.

Safety measures before use

- Before using the catheter or external pacemaker, you must read and understand the respective instructions for use.
- When connecting external devices and using them for their specific purpose, consult the corresponding instructions for use. Only use authorised medical devices under consideration of the respective instructions for use.
- All static electricity must be kept away from the catheter system. You must also take particular care to ensure that the operating table and the electronic devices which are used (e.g. X-rays) are earthed sufficiently and centrally.
- A prerequisite for making an intracardiac potential recording and/or stimulation is the appropriate training of medical staff and the availability of a fully equipped electrophysiology laboratory. The procedure itself may only be carried out by a trained, experienced physician.
- The use of this catheter in pregnant women must be carefully considered.

Removal from packaging

→ Check that the packaging is not damaged.

→ Take the catheter out under aseptic conditions and transfer it to a sterile working environment.

→ Ensure that the packaging material is disposed of safely.

→ Check the catheter for any obvious defects such as kinks in the shaft, loose electrodes or damaged plugs and, if necessary, swap it for another catheter. The catheter must not be used if there is any obvious damage.

→ Carry out a careful visual inspection and functional inspection of the plug.

Application

✓ In order to avoid injuring the ventricular system and the heart, the intervention must always be carried out under X-ray control.

✓ An external pacemaker and a defibrillator must be available and ready for use throughout the entire procedure.

✓ The principles of asepsis must be observed.

→ Apply the standard method for vessel punctures, introduction of a guide wire and the application of an introducer sheath in compliance with the instructions for use.

→ Connect the catheter to a suitable recording device with an appropriate connection cable.
→ Before inserting and removing the catheter, ensure that the thumb switch used to control the tip curvature is fully retracted. Guide and monitor the catheter movements within the patient with X-ray imaging and electrocardiograms.

NOTE: The catheter may only be inserted into or removed from the introducer sheath with a straight tip.

NOTE: In order to make positioning the catheter tip easier, it can be bent using the thumb switch. To do this, push the thumb switch forward. If you push the thumb switch backwards, the tip will straighten itself again. The catheter is straight when the thumb switch is pushed back fully and can then be removed.

NOTE: If resistance occurs, the catheter must not be pulled back with force. In this case, an X-ray must be used to check the position of the catheter.

NOTE: Excessive manipulations such as kinking and bending the shaft, as well as pre-bending the curvature could lead to damages to the catheter or the catheter control unit.

Disposal

The catheter is to be disposed of in accordance with the applicable national laws and directives.

Contraindications

The application of the Vanguard Steerable Diagnostic Catheter SJA and the Vanguard Steerable Diagnostic Catheter SJF are contraindicated for the following:

- patients who have undergone a ventriculostomy or atriotomy in the preceding four weeks
- transseptal access for patients with thrombus or myxoma in the left ventricle or with an intracardiac patch or baffle
- retrograde transaortic access in patients with an aortic valve prosthesis
- patients who have shown sensitivity to foreign objects in the past or who have an allergy
- patients with severe anomalies in the heart and/or blood vessels (transposition) and obstruction

An active systemic infection is considered to be a relative contraindication; therefore, an examination should only be carried out after a rigorous risk/benefit assessment by the treating physician.
Ablations may not be performed with the catheter.

Side effects

When using the catheter, breakage of the catheter, dislocation of the catheter, contact problems between the catheter and pacemaker and an increase in the stimulus threshold can cause the following undesired side effects:

- pain and discomfort in the chest
- increase in phosphokinase levels
- subcutaneous haematoma
- stimulation of skeletal muscles and nerves
- lesion of the brachial plexus
- lesion of the thoracic duct
- lesion of the intracardiac conduction system
- damage to heart valves and/or blood vessels (e.g. venous supplies)
- local and systemic infection
- pneumothorax due to subclavian puncture
- haematothorax
- pericarditis
- cardiac tamponade
- arteriovenous fistula
- pseudoaneurysms
- arrhythmias (e.g. ventricular tachyarrhythmias)
- cardiac thromboembolism, air embolisms
- perforation of the atrium or ventricle (myocardium/endocardium) with or without loss of simulation or ventricular fibrillation
- coronary artery spasm, coronary artery thrombosis, coronary artery transsection
- transient ischaemic attack (TIA) and apoplectic stroke
- pulmonary embolism
- myocardial infarction
- total heart block
- death

Previously unknown side effects may occur at any time. The distributing company must be notified of any side effects that are not specified.
In connection with the known side effects, please also refer to the relevant specialist literature.