INSTRUCTIONS FOR USE

Vanguard Variable Loop Diagnostic Catheter SJC

Vanguard Variable Loop Diagnostic Catheter EB SJE

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CE 0086

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 under the e-mail address service@vanguard.de or speak to our external sales 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 Variable Loop Diagnostic Catheter SJC” or “Vanguard Variable Loop Diagnostic Catheter EB SJE” and/or disregard of these instructions for use.

VANGUARD AG and the manufacturer of the original product, St. Jude Medical, Inc. (2375 Morse Avenue, Irvine, CA92614 USA), 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" is a protected brand 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 Variable Loop Diagnostic Catheter SJC or
One (1) Vanguard Variable Loop Diagnostic Catheter EB SJE

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

	Do not reuse
	Do not resterilize
	Do NOT use if the sterile packaging is damaged or opened
	Sterile, sterilisation using ethylene oxide
	Expiry date
	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 mark with identification number of the notified body
	Manufacturer
	Item number

PRODUCT DESCRIPTION

The Vanguard Variable Loop Diagnostic Catheter SJC and Vanguard Variable Loop Diagnostic Catheter EB SJE consist of a torsion-resistant shaft and proximally, of a steerable area (curvature) with a width-adjustable loop with several attached electrodes. Vanguard Variable Loop Diagnostic Catheter EB SJE has an extended braid (EB) shaft. This catheter is intended for temporary intracardiac recording of potentials, stimulation of the heart during electrophysiological examinations and for mapping of the heart's atrial structures.

The curvature of the proximal shaft area is controlled by a movable plunger with a thumb knob in the hand piece of the catheter. To adjust the curvature, the thumb knob is pushed forward. When the thumb knob is in the rear position, the curvature is straight. The designation of the curvature corresponds to the designation of the original manufacturer St. Jude: “SM-OPTxx“. The loop width can be adjusted within a certain range using a rotary knob. To constrict the loop, turn the knob in clockwise direction, and turn it again in anti-clockwise direction to expand the loop.

An extension cable with an appropriate plug connector should be used to connect it to a suitable standard recording device.

Intended use
The Vanguard Variable Loop Diagnostic Catheter SJC and Vanguard Variable Loop Diagnostic Catheter EB SJE are intended for temporary intracardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations. 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 Variable Loop Diagnostic Catheter SJC and Vanguard Variable Loop Diagnostic Catheter EB SJE have the same compatibility with accessories as the corresponding products of the original manufacturer St. Jude Inc., USA.

Technical data

Vanguard Variable Loop Diagnostic Catheter SJC

Shaft diameter: 7 F
Usable length: ≥ 110 cm
Connection: 14-pin or 26-pin (Redel)

Item No.	Corresponding REF-No. of original manufacturer	Curve type	Electrodes			Connection (corresponds to St.Jude cable)
			Quantity	Width TE / BE[1] [mm]	Distance [mm]	
34395	IBI-81687	SM-OPT25	10	2 / 1	7	14-pin (1910-S)
34447	IBI-81683	SM-OPT25	20	2 / 1	1(4.5)	26-pin (1924-S)
34449	IBI-81717	SM-OPT25	24	2 / 1	1(4.5) - 20(3)	26-pin (1924-S)

Other data → see label

Vanguard Variable Loop Diagnostic Catheter EB SJE

Shaft diameter: 7 F
Usable length: ≥ 110 cm
Connection: 14-pin or 26-pin (Redel)

Item No.	Corresponding REF-No. of original manufacturer	Curve type	Electrodes			Connection (corresponds to St.Jude cable)
			Quantity	Width TE / BE[1] [mm]	Distance [mm]	
34446	IBI-81767	SM-OPT25	10	2 / 1	7	14-pin (1910-S)
34448	IBI-81695	SM-OPT25	20	2 / 1	1(4.5)	26-pin (1924-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.

[1] TE = Tip Electrode, BE = Band Electrodes

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.	
1910-S	85930	10-Pin Diagnostic Connection Cable 150cm
1924-S	85931	24-Pin Diagnostic Connection Cable 150cm

CE 0086

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

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, sepsis

→ 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 knob 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 knob backwards to insert or remove the catheter in order to put the proximal catheter end into a straight position. Turn the rotary knob in clockwise direction to expand the loop.

→ 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.

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.

→ The catheter should be guided into the required cardiac areas via the peripheral vessels.

→ 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 knob used to control the curvature is fully retracted and that the loop is extended. Guide and monitor the catheter movements within the patient with X-ray imaging and electrocardiograms.
→ Extend the "loop" with your thumb and forefinger to introduce it into the sheath. Once the loop has passed the sheath, it will resume its specified shape.

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

NOTE: In order to make positioning the proximal catheter end easier, it can be bent using the thumb knob. To do this, push the thumb knob forward. If you push the thumb knob backwards, the proximal catheter end will straighten again. The catheter is straight when the thumb knob 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 Variable Loop Diagnostic Catheter SJC or Vanguard Variable Loop Diagnostic Catheter EB SJE is contraindicated for the following:

- use in ventricles
- a retrograde access
- patients with a parietal thrombus
- patients who have undergone a ventriculostomy or atriotomy in the preceding four weeks
- patients with heart valve prosthesis
- transseptal access for patients with myxomas in the left ventricle or with an intracardiac patch or baffle
- 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
- haemothorax
- 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 transection
- 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.