I N S T R U C T I O N S F O R U S E

Vanguard Steerable Diagnostic Catheter BSA
Vanguard Steerable Diagnostic Catheter BSB

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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 under the e-mail address service@vanguard.de before using the product on patients or consult our sales representative.

General information

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

✓ Requirements

→ Instructions

• Lists

⚠ Safety instructions

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

Device information

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

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

Vanguard AG and the manufacturer of the original product, Boston Scientific Corporation (300 Boston Scientific Way Marlborough, MA 01752-1234 USA), are not affiliated companies; the device is fully refurbished solely by Vanguard AG, who markets the device without collaboration by the Boston Scientific Corporation.

Packaging labelling and symbols

Content: one (1) Vanguard Steerable Diagnostic Catheter BSA/ BSB

The medical device may only be used until the specified "Use-by-date date" (⌛).

	Do not reuse
	Do not resterilize
	Do NOT use if the [sterile] packaging is damaged or opened
STERILE EO	Sterile, sterilization with ethylene oxide
	Use-by-date
SN	Serial number
	Store away from sunlight
	Keep in a dry place
	Storage temperature limits
	Consult the instructions for use
CE 0481	CE Mark with identification number of notified body
	Manufacturer
REF	Article number

PRODUCT DESCRIPTION

The Vanguard Steerable Diagnostic Catheters BSA/ BSB are catheters with several electrodes and flexible tip. These catheters are designed for temporary intracardiac recording of potentials and temporary stimulation of the heart. The catheters are not suitable for ablation.

The catheters are fitted with a high torque shaft and a flexible tip that includes several electrodes. These electrodes can be used for recording and stimulation purposes.

For the Vanguard Steerable Diagnostic Catheter BSA the curvature of the tip is controlled by a movable plunger with a thumb knob on the handle at the proximal end of the catheter. The thumb knob is pushed forward to curve the tip. The tip is straight when the thumb knob is in the rear position.

The curvature of the Vanguard Steerable Diagnostic Catheter BSB is controlled by a rotation knob on the proximal catheter handle. To bend the tip, the rotation knob is rotated in clockwise direction. The tip is straightened by rotating the knob in counterclockwise direction.

The plane of the curved tip can be rotated by turning the shaft. This allows the practising physician to make use of both the bending of the tip and the rotation. This enables them to position the catheter tip in the ventricles of the heart as required in order to carry out the desired procedures safely. An extension cable with an appropriate plug connector can be used to connect it to a suitable recording device.

Intended use

The Vanguard Steerable Diagnostic Catheters BSA/ BSB are intended for temporary intracardiac ECG recording and stimulation (mapping) of the heart within the scope of electrophysiological examinations.

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 cardiologist specialized in electrophysiology.

All Vanguard Steerable Diagnostic Catheter BSA/ BSB are compatible with accessories (e.g. generator and cables) as the corresponding products of the original manufacturer Boston Scientific Corporation (refer to technical data).

Technical data Vanguard Steerable Diagnostic Catheter BSA

Curve type: Large 4.0
Diameter: Schaft 6F
Useable length: 110 cm

Article No.	Corresponding REF no. of the original product	Tip electrode length [mm]	Ring electrodes			Connection
			Quantity	Length [mm]	Distance [mm]	
33263	M004 2011010	2	9	1	2, 5, 2	10 PIN (SureLink)
33382	M004 2011020	2	9	1	2, 6, 2	10 PIN (SureLink)
33383	M004 2011030	2	3	1	2, 5, 2	4 PIN (Easy-Mate)
33384	M004 2011040	2	3	1	5	4 PIN (Easy-Mate)
33385	M004 2011050	2	7	1	2, 5, 2	8 PIN (Easy-Mate)
33386	M004 2011060	2	7	1	2	8 PIN (Easy-Mate)
33387	M004 2011070	2	7	1	5	8 PIN (Easy-Mate)
33388	M004 2011080	2	7	1	2, 10, 2	8 PIN (Easy-Mate)
33389	M004 2011100	2	3	1	10	4 PIN (Easy-Mate)
33390	M004 2011120	2	3	1	2	4 PIN (Easy-Mate)
33391	M004 2011130	2	5	1	5	6 PIN (Easy-Mate)

Other data ➔ see label.

Technical Data Vanguard Steerable Diagnostic Catheter BSB

Curve type: Large 4.0
Diameter: Shaft 6F
Usable length: 110 cm

Article No.	Corresponding REF no. of the original product	Tip electrode length [mm]	Ring electrodes			Connection
			Quantity	Length [mm]	Distance [mm]	
34992	M004 2010070	2	9	1	2, 5, 2	10 PIN (SureLink)
34988	M004 2007940	2	7	1	2, 5, 2	8 PIN (Easy-Mate)
34989	M004 2007950	2	7	1	2	8 PIN (Easy-Mate)
34990	M004 2007960	2	7	1	5	8 PIN (Easy-Mate)
34991	M004 2007970	2	7	1	2, 10, 2	8 PIN (Easy-Mate)

Other data ➔ see label.

The catheters are used in conjunction with compatible connection cables from Boston Scientific Corporation (300 Boston Scientific Way Marlborough, MA 01752-1234) and suitable devices.

"SureLink" and "Easy-Mate" are registered trademarks of the manufacturer of the original product Boston Scientific Corporation (300 Boston Scientific Way Marlborough, MA 01752-1234 USA) or of a manufacturer associated with this company.

CE 0481

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, and countermeasure. A safety instruction indicates a potential risk to the health or life of persons.

⚠ 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.

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

Liquid penetration and impairment with the function of the catheter

→ Prevent the plug, the cable and the handle from coming into contact with liquids.

⚠ Plug contacts touched or comes into contact with thin objects!

Impairment with the function of the catheter

→ Ensure that no thin objects come in contact with the plug. Don’t touch the plug contacts.

⚠ The medical personnel have not been adequately trained!

Fault when making intracardiac potential recordings and/or stimulation.

→ It is a pre-requirement for intracardiac potential recording and/or stimulation that

specialist medical personnel are trained sufficiently and that a fully equipped electrophysiology laboratory is present. The procedure itself may only be carried out by a trained and experienced cardiologist specialized in electrophysiology.

⚠ Insufficient caution when handling the catheter!

Injuries of the heart, perforation or tamponades.

→ Take great care when handling the catheter.

⚠ Ignition of flammable gases and other substances!

Fire or explosion.

→ Ensure that that flammable and easily inflammable materials are removed from the working area.

⚠ Plug connector damaged!

Extension of the surgery time

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

⚠ Electromagnetic interference due to an external pacemaker!

Damage or impairment of other devices/ventricular fibrillation and burns

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

⚠ 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.

⚠ Misplacement of the catheter into the coronary system during transaortic access!

Increased risk of bleeding, shock or myocardial infarction

→ Ensure that there is good imaging during transaortic access.

⚠ 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.

⚠ Sterile packaging 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 continued use contrary to the intended use and due to unsuitable storage conditions!

Damage to the central circulatory system, infection, septicaemia

→ Observe the intended use and corresponding information on the package.

⚠ Improper use of the catheter or incorrect operation of the control elements of curvature adjustment!

Injuries, perforations and tamponades in the heart and vascular system

→ Ensure that only trained personnel uses the catheter.
→ Vanguard Steerable Diagnostic Catheter BSA: Always push the thumb knob back when inserting or removing the catheter to bring the catheter tip to a straight position.
→ Vanguard Steerable Diagnostic Catheter BSB: Always push the thumb knob 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.
→ The catheter must not be subjected to any mechanical stress caused by manual deformation.
→ The control knob may not be lubricated.

⚠ Reprocessing, re-sterilization reuse and/or technical modification of the catheter by the user or operator!

Injury to blood vessels and intracardiac injuries, infection, sepsis, death of the patient

→ The Vanguard Steerable Diagnostic Catheters BSA/ BSB are disposable products and only intended for single use on one patient.
→ The catheter may not be reprocessed, re-sterilized and reused by the user or operator.
→ The catheter may not be technically modified.

⚠ Devices with leakage currents are operated in the immediate vicinity of the patient!

Leakage currents on catheters, lethal arrhythmias

→ Ensure that no devices with leakage currents are located and operated in the immediate vicinity of the patient.

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

The product must be stored in a cool, dry and light-protected area. Storage temperatures range from 5 °C to 25 °C.

→ Information about storage conditions is also provided 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.
- Observe the relevant instructions for use when connecting and using external devices. Only use approved medical devices while observing the 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.
- It is a pre-requirement for intracardiac potential recording and/or stimulation that specialist medical personnel are trained sufficiently and that a fully equipped electrophysiology laboratory is present. The procedure itself may only be carried out by a trained and experienced cardiologist specialized in electrophysiology.

Removal from packaging

→ Check that the packaging is not damaged. If packaging and the sterilization barrier are damaged, the product must be disposed of and another device must be used for the procedure.

→ 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.

→ Submit the plug to a thorough visual and functional inspection and replace the catheter if necessary.

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.

→ Under consideration of the aseptic rules, access a large central blood vessel through which you can push the catheter in.

→ Connect the catheter to a suitable recording device with an appropriate connection cable.

→ Using an X-ray and electrocardiogram as guidance, push the catheter forwards and position it in the required place in the endocardium.

NOTE: To simplify positioning of the catheter tip, the Vanguard Steerable Diagnostic Catheter BSA can be curved using the thumb knob. To do this, push the thumb knob forward. Push the thumb knob back to straighten the tip again. The catheter is straight when the thumb knob is pushed completely back and can then be removed.

NOTE: In order to simplify catheter tip positioning, the Vanguard Steerable Diagnostic Catheter BSB can be bent using the control knob by rotating it in clockwise direction. In this case, the catheter tip points in distal direction. If the control knob is rotated in anticlockwise direction, the tip returns to its upright position. The catheter is straight when the white indicator dot is visible in the window of the handle. The catheter can be inserted or removed in this state.

NOTE: If resistance occurs, the catheter must not be pulled back with force. In this case, the catheter position must be checked by X-ray examination.

NOTE: The catheters may only be used with approved recording devices and generators that are compatible with appropriate catheters made by Boston Scientific Corporation. Observe the information and Technical Manual of the equipment manufacturer. Use the cables supplied by Boston Scientific Corporation that are intended for use with the corresponding catheters made by the same company.

Safety measures after use

Following the clinical procedure, the catheter must be checked for intactness for patient safety purposes. Pay attention to breaks and fragmentation of the shaft and tip. All actively implanted devices of the patient must be checked for functionality.

Disposal

Any used product must be considered as contaminated hospital waste. The catheter is to be disposed of in accordance with the applicable national laws and directives.

Contraindications

The use of a Vanguard Steerable Diagnostic Catheter BSA/ BSB is contraindicated for:

- patients with an intracardiac parietal thrombus
- Patients who have undergone ventriculotomy or atriotomy in the past four weeks
- patients with heart valve prosthesis
- transseptal access for patients with 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

- patients with active systemic infection

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 fistulae
- 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
- myocardial infarction
- total heart block
- death

Previously unknown side effects may occur at any time. In this case, the events that occur are to be reported to the distributor.
In connection with the known side effects, please also refer to the relevant specialist literature.