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

Vanguard Steerable Diagnostic Catheter BWC
Vanguard Steerable Diagnostic Catheter BWD
Vanguard Steerable Diagnostic Catheter BWE
Vanguard Steerable Diagnostic Catheter BWF

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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.

Product specifications

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

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

Vanguard AG and the manufacturer of the original product, Biosense Webster Inc. (3333 Diamond Canyon Road, Diamond Bar, California 91765, USA)are not affiliated companies; the device is remanufactured solely by Vanguard AG, who markets the device without collaboration by Biosense Webster Inc. "Biosense Webster", "WEBSTER", "PARAHISIAN", "CRISTA CATH" and "ISMUS CATH" are protected brands of the manufacturer of the original product Biosense Webster Inc., USA or one of its affiliated companies.

Packaging label and symbols

Content:
One (1) Vanguard Steerable Diagnostic Catheter BWC/BWD/BWE/BWF
The medical device may only be used until the specified "Use by date" ().

	Do not reuse
	Do not resterilize
	Do **NOT** use if the sterile packaging is damaged or opened
	Sterilisation using ethylene oxide
	Use by date
	Serial number
	Keep away from sunlight
	Store in a dry place
	Information about acceptable ambient temperature during storage and transportation
	Consult instructions for use
	CE mark with identification number of Notified Body
	Manufacturer
	Item number

PRODUCT DESCRIPTION

The Vanguard Steerable Diagnostic Catheter BWC/BWD/BWE/BWF is a catheter with multiple electrodes and a flexible tip. This catheter is intended for temporary intracardiac recording of potentials and temporary stimulation of the heart using an external pacemaker. The catheter cannot be used for ablation.

The catheter is fitted with a high torque shaft and a flexible tip that includes several electrodes. The electrodes can be used for conduction and stimulation purposes.

The curvature of the tip is controlled by a movable plunger with a thumb switch in the handpiece at the proximal end of the catheter. The thumb switch is pushed forward to curve the tip. The tip is straight when the thumb switch is in the rear position. The deflection of the tip depends on the length of the steerable tip and the position of the thumb switch. Catheters with different deflections of the tip are available (see section technical data). The name of the type of the tip corresponds to the name of the original manufacturer, Biosense Webster Inc. The level at which the curved tip is positioned can be rotated by turning the shaft. This allows the practising physician to make use of tip curvature as well as rotation. It is thereby possible to position the catheter tip in the ventricles as required in order to be able to safely carry out the desired procedures. An extension cable with a suitable connector is used to connect to a suitable standard recording device.

Intended use

The Vanguard Steerable Diagnostic Catheter BWC/BWD/BWE/BWF is designed for temporary intracardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations.

It is the responsibility of the physician to use an appropriate surgical procedure and technique. The procedure described in the instructions for use is only for information. 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.

Technical data

Vanguard Steerable Diagnostic Catheter BWC, 6F

Shaft diameter: 6 F
Useable length: 92 cm
Connection: 10 PIN (Redel)

Item no.	Corresponding REF No. of the original manufacturer	Tip electrode length [mm]	Curve type	Ring electrodes	
				Number	Distance [mm]
33576	36B38R	1	D	3	2-5-2
33577	36B33R	1	D	3	5
33579	36E30Q	1	D	5	2,5-4-2,5-2,5-2,5
33569	36S30Q	1	D	7	2-10-2-2-2-5-2
33570	36S31Q	1	D	7	2
33571	35X33Q	1	D	9	2-8-2
33572	35X38Q	1	D	9	2-5-2
33573	35X58Q	1	F	9	2-5-2

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.

Vanguard Steerable Diagnostic Catheter BWC, 7F

Shaft diameter: 7 F
Useable length: 115 cm
Connection: 10 PIN (Redel)

Item no.	Corresponding REF No. of the original manufacturer	Tip electrode length[mm]	Curve type	Ring electrodes	
				Number	Distance[mm]
33578	36C38R	1	D	3	2-5-2
33574	36F30Q	1	D	7	2
33575	36G33Q	1	D	9	2-8-2

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.

Vanguard Steerable Diagnostic Catheter BWD, 7F

Shaft diameter: 7 F
Useable length: 90 cm
Connection: 8 PIN (Redel)

Item no.	Corresponding REF No. of the original manufacturer	Tip electrode length [mm]	Curve type	Ring electrodes	
				Number	Distance [mm]
33787	36L00Q	1	D	8	2,5-10-2,5-2,5-2,5-2,5-2,5-2,5

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.

Vanguard Steerable Diagnostic Catheter BWF, 7F

Shaft diameter: 7 F
Useable length: 115 cm
Connection: 10 PIN (2) (Redel)

Item no.	Corresponding REF No. of the original manufacturer	Tip electrode length [mm]	Curve type	Ring electrodes	
				Number	Distance [mm]
33941	36Y39R	3	D	19	1-3-1

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.

Vanguard Steerable Diagnostic Catheter BWE, 7F

Shaft diameter: 7 F
Useable length: 110 cm
Connection: 10 PIN (2) (Redel)

Item no.	Corresponding REF No. of the original manufacturer	Curve type	Ring electrodes	
			Number	Distance [mm]
33942	36Y32R	Isthmus-Type	20	2-12-2

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 conjunction with compatible connection cables provided by Biosense Webster, Inc. and suitable devices for electrophysiological mapping (recording signals and stimulation).

CE 0481

This product has a CE mark in compliance with the regulations of EU Directive 93/42/ECC and all applicable ammendments.

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.

⚠ Excessive bending or kinking of the catheter!

Liquid penetration and impairment with the function of the catheter, damage to the wires and/or injury of the patient

→ Prevent kinking of the catheter shaft or excessive bending.
→ Do not bend the distal tip manually.

⚠ Proximal connector or handle is in contact with liquid!

Impairment with the function of the catheter

→ Prevent the connector from coming into contact with liquids.

⚠ Plug connector damaged!

Impairment with electrical safety and function

→ Carry out a careful visual and functional test of the connector

⚠ 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 connected cables with your fingers or objects.
→ Only connect the plug contacts of the catheter to the suitable medical devices using proper connection cables.
→ Do not allow the connectors of the catheter or a connection cable to come into contact with liquids. This could affect electrical safety and functionality.

⚠ 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!

Bleeding, shock or heart attack

→ Ensure good imaging during transaortic access.

⚠ Long fluoroscopy times with X-rays!

Somatic and genetic damage due to high exposure to ionising radiation

→ Review the benefit/risk ratio due to the possible radiation effects especially for pregnant women, children and adolescent patients, and patients undergoing multiple examinations.

⚠ Sterilised package is damaged or opened!

Infection of patients by non-sterile products

→ Check the package before you open it and do not use the catheter if damaged.

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

Injury to the central circulatory system, infection, sepsis

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

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

→ Do not autoclave the catheter.

⚠ Improper use of the catheter or incorrect operation of the thumb switch!

Injury, perforation and tamponade of the heart and the vascular system

→ Ensure that the catheter is only used by trained users.

→ Always push the thumb switch back when inserting or removing the catheter to bring the catheter tip to a straight position.

→ Do not forcefully push the catheter forwards or back if you encounter resistance.

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

Injury to blood vessels and intracardial injuries, infection, sepsis

→ Ensure that the catheter is not reprocessed, resterilized and reused by the user or operator.

HANDLING INSTRUCTIONS

Handling the catheter requires extreme care to avoid injury, perforation and tamponade of the heart and vascular system.

Storage

→ Handling the catheter requires extreme care to avoid injury, perforation and tamponade of the heart and vascular system.

Safety measures before use

- The relevant instructions for use must be read and understood before using the catheter or the external pacemaker.
- Observe the relevant instructions for use when connecting and using external devices. Only use approved medical devices while observing the instructions for use.
- Any static electricity must be kept away from the catheter system. Special care must also be taken to provide adequate and central grounding of the operating table and the electrical devices used (e.g. X-ray machines).
- 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 must only be performed by a trained and experienced physician.

Unpacking

→ Check the packaging for damage. If the packaging is damaged the product has to be deposited and another new product for the procedure is to use.

→ Remove the catheter under aseptic conditions and transfer it to a sterile working area.

→ Make sure that the packaging material is disposed of safely.

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

→ Carry out a careful visual and functional test of the connector and replace the catheter if necessary.

Application

- ✓ The procedure must always be performed under radiographic monitoring to avoid injury to the vascular system and heart.
- ✓ An external cardiac pacemaker and a defibrillator must be available for use during the entire procedure.
- ✓ The principles of asepsis should be observed.

- → Observing aseptic rules, access to a large central vessel is to be established where the catheter can be inserted.
- → Connect the catheter with the appropriate connection cable to a suitable recorder.
- → Push the catheter under radiographic monitoring and ECG and position it at the desired location of the endocardium.

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

NOTE: Do not forcefully withdraw the catheter if resistance is encountered. In this case, the catheter position must be checked by X-ray examination.

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 BWC/BWD/BWE/BWF is contraindicated for the following:

- Patients with 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 atrium or with intracardiac patch or baffle.
- Retrograde transaortic access for patients with an aortic valve prosthesis
- Patients who in the past have shown sensitivity to foreign objects or who have allergies
- Patients with massive anomalies of the heart or 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.

Side effects

The following undesirable side effects may occur due to catheter fracture, catheter dislocation, contact problems between the catheter and pacemaker and due to an increase in the stimulus threshold:

- Pain and discomfort in the chest
- Increase in phosphokinase values
- Subcutaneous haematoma
- Skeletal muscle and nerve stimulation
- Lesion of the brachial plexus
- Lesion of the thoracic duct
- Lesion of the intracardiac conduction system
- Damage to heart valves and/or vessels (e.g. veins)
- Local and systemic infection
- Pneumothorax in case of subclavia puncture
- Haemothorax
- Pericarditis
- Cardiac tamponade
- Arteriovenous fistulae
- Pseudoaneurysms
- Arrhythmias (e.g. ventricular tachyarrhythmias)
- Cardiac thromboembolism, air embolism
- Perforation of the atrium or ventricle (myocardium / endocardium) with or without loss of stimulation or ventricular fibrillation
- Coronary artery spasm, coronary artery thrombosis, coronary artery transection
- Transient ischaemic attack (TIA) and apoplectic stroke
- Myocardial infarction
- Complete heart block
- Death

It is always possible that previously unknown side effects may occur. The distributing company must be notified of any side effects that are not specified.
Known side effects are also referred to in the relevant specialist literature.