INSTRUCTIONS FOR USE

Vanguard Ablation Catheter bi BWB
Vanguard Ablation Catheter bi DS BWQ

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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 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

Product specifications

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

VANGUARD assumes no liability for damages that arise from improper operation of the Vanguard Ablation Catheter bi BWB/DS BWQ and/or disregard of these instructions for use.

VANGUARD AG and the manufacturer of the original product, Biosense Webster, Inc. (33 Technology Drive Irvine, California 92618, USA) are not affiliated companies; the device is remanufactured solely by Vanguard AG, who markets the device without collaboration by Biosense Webster, Inc.

Packaging label and symbols

Content:
One (1) Vanguard Ablation Catheter bi BWB/DS BWQ.
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 EO	Sterilisation using ethylene oxide
	Use by date
SN	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 0086	CE mark with identification number of Notified Body
	Manufacturer
REF	Item number

PRODUCT DESCRIPTION

The Vanguard Ablation Catheter bi BWB/DS BWQ is a catheter with multiple electrodes and a flexible tip. This catheter is intended for electrophysiological mapping of the heart and conducts an alternating current into the tissue via the distal catheter tip for the purpose of ablation. An appropriate generator and reference electrode are necessary to perform ablation.

There is at least one temperature sensor in the catheter tip that can be used to monitor temperature during ablation. The temperature sensor is integrated in the large tip. There is one temperature sensor in the tip of the Vanguard Ablation Catheter bi BWB and two temperature sensors in the catheter tip of the Vanguard Ablation Catheter bi DS BWQ. The catheter is fitted with a torsion-resistant shaft with a flexible tip that includes multiple electrodes. The electrodes can be used for conduction and stimulation purposes.

The handle consists of the two half-shells from the handle body. They surrounded an inner structure for curvature adjustment and surrounded the plug. There are two control elements (a rocker lever and a locking screw) for the adjustment at the handle. The curvature will be fixed or released with the locking screw and curved with the rocker lever. There are five different types of curvature D-D, D-F, F-F and F-J. The level at which the curved tip is positioned can be rotated by turning the shaft. This allows the practicing physician to make use of tip curvature as well as rotation to reach a certain position of the catheter tip in the ventricles. The catheter is used in combination with suitable recorders and compatible RF-generators. Use a suitable plug connection to connect the appropriate extension cables.

Intended use

The Vanguard Ablation Catheter bi BWB/DS BWQ is designed for temporary intercardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations, in conjunction with compatible connection cables from the Biosense Webster, Inc. Company and suitable devices for electrophysiological mapping. All Vanguard Ablation Catheter bi BWB/DS BWQ are intended for use with compatible RF generators and 8F introducer sheaths. For dispersive electrodes read and follow the manufacturer instruction for use. It is recommended that dispersive electrodes are meets or exceed the requirements according EN 60601-2-2.

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 Ablation Catheter bi DS BWQ

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

Item no.	Corresponding REF-No. of original manufacturer	Tip electrode length	Curve type	Ring electrodes		Temperature sensor
				Number	Distance	
34772	35U33R	8 mm	D-D	3	1,7,4 mm	Thermocouple
34773	35U35R	8 mm	D-F	3	1,7,4 mm	Thermocouple
34774	35U55R	8 mm	F-F	3	1,7,4 mm	Thermocouple
34775	35U5JR	8 mm	F-J	3	1,7,4 mm	Thermocouple

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 Ablation Catheter bi BWB

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

Item no.	Corresponding REF-No. of original manufacturer	Tip electrode length	Curve type	Ring electrodes		Temperature sensor
				Number	Distance	
34776	35I33R	4 mm	D-D	3	1,7,4 mm	Thermocouple
34777	35I35R	4 mm	D-F	3	1,7,4 mm	Thermocouple
34778	35I5JR	4 mm	F-J	3	1,7,4 mm	Thermocouple

Other data → see label

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

Proximal connector or handle is in contact with liquid!

Impairment with the function of the catheter

→ Prevent the connector and the handle 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

Temperature or impedance set point exceeded!

Interruption or influence of the ablation current

→ Bring the catheter tip to a straight position with the curvature control and then pull it out and clean coagulation deposits from the tip. Leave the electrode tip in a straight position when cleaning. Avoid rotating or rubbing to prevent damage to the connection point and the electrode tip or the electrodes becoming loose.

More than 30 ablations conducted, each with one minute of energy supply!

Hazard due to loss of function or loose tip electrode

→ Do not perform more than 30 ablations at a time with an energy supply of over one minute or less.

No anticoagulant is administered!

Application for thromboembolism

→ Administer intravenous heparin in the left ventricle during access for ablation purposes. There is still no consensus concerning of the need to use anticoagulants after ablation.

The medical personnel have not been adequately trained!

Fault when making intracardiac potential recordings and/or stimulation

→ 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.

Lack of care when handling the catheter!

Injuries of the heart, perforation or tamponade

→ Take great care when handling the catheter.

⚠ Dispersive electrode(s) improperly attached, incorrect electrodes or failure of electronic cables!

Low power delivery, increased impedance or equipment malfunction despite correct device settings

→ Ensure that the dispersive electrodes and their connectors are correctly attached. Check the device for faults or incorrect attachment before you increase the energy supply in the case that the power delivery is too low.

→ The dispersive electrodes used should comply with or exceed the regulations according EN 60601-2-2.

⚠ Improper handling of the catheter, generator or accessories!

Injury to the patient and/or medical personnel and/or technical facilities

→ The relevant instructions for use must be read and understood before using the catheter or the external pacemaker.

→ 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).

⚠ Conductive paths created for ablation alternating currents via the electrodes and probes of monitoring or stimulation instruments!

Risk of burns

→ To reduce the risk of burns, position the electrodes and probes as far away as possible from the ablation site and dispersive electrodes.

⚠ Ignition of flammable gases and other substances!

Fire or explosion

→ Make sure that highly flammable substances are removed from the working area.

⚠ The generator does not display a temperature for the catheter version with a temperature sensor!

Temperature control/monitoring not possible for ablation

→ Check the cable connection at the generator. If the temperature is not displayed, there may be a malfunction in the temperature sensor system. Rectify this fault before applying RF current.

⚠ 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 interference 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.

⚠ The long-term risks that are associated with high frequency lesions have not yet been proven!

Unclear risks and long-term risks

→ This should only be applied on prepubertal children after thorough consideration.

⚠ 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.

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

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

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

→ Always use the curvature control 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/resterilisation and reuse after indented use of the catheter by the user or operator is to avoid!

Injury to blood vessels and intracardial injuries, infection, sepsis

→ The catheter is not to be reprocessed, resterilized or reused by the operator or user.

Use of RF current!

⚠ **Impairment of implantable pacemakers and automatic implantable cardioverter/defibrillators (AICDs)**

→ An external cardiac pacemaker and a defibrillator must be available for use during the entire procedure.

→ Temporarily reprogram the pacemaker system to the minimum delivery or OFF to minimise the risk of an undesired stimulation.

→ Take the utmost care when the ablation point is in the vicinity of the atrial or ventricular electrodes. In this case, program the AICD to the OFF mode during ablation and perform a full test of the implanted equipment after the procedure has been completed.

⚠ Ablation at a septal accessory pathway!

Total AV block

→ Only perform ablation at septal accessory conduction pathways after a strict risk/benefit assessment, as the risk of a total AV block requires the implantation of a permanent pacemaker.

→ An external cardiac pacemaker and a defibrillator must be available for use during the entire procedure.

HANDLING INSTRUCTIONS

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

Storage

→ The details on the storage conditions are shown on the product packaging label.

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.

Removal from packaging

- Check that the packaging is not damaged. If the packaging is damaged the product has to be deposited and another new one product for the procedure is to use.
- Take the catheter out under aseptic conditions and transfer it to a sterile working environment.
- Make sure 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 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 compatible recorder and/or generator.

→ 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 curvature control. The curvature will be fixed or released with the locking screw and curved with the rocker lever. The catheter is straight when the rocker lever is in the base position 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.

NOTE: In order to perform ablation under RF current, a secure connection of the catheter and the RF generator is necessary. To do this, only use the connection cable from the Biosense Webster, Inc. and also read the technical manual of the RF generator.

NOTE: To perform ablation, the tip electrodes must be connected to the catheter tip at the current output connection for ablation at the RF generator. You can find more information in the technical manual of the relevant RF generators.

NOTE: To close the electric circuit, the neutral electrode must be connected to the reference electrode input of the RF generator. The electric circuit impedance should be 100 Ω before the start of ablation. The RF generator should display a temperature of approx. 37 °C for catheters with a temperature sensor after introduction in the cardiovascular system and before starting ablation.

NOTE: The multiple delivery of RF current can lead to coagulation residues on the catheter tip. This is noticeable by the increase in temperature and impedance, and can also lead to the automatic shutoff of the generator. In this case, the catheter must be removed in order to clean the electrode. Use a sterile saline solution (0.9 %) or sterile Ringer's solution. Carefully clean just the tip and do not rub or bend it to avoid damaging or loosening the tip. Please also read the safety instructions.

NOTE: The catheters may only be used with approved recorders and generators that are compatible with appropriate catheters made by Biosense Webster, Inc. Observe the information and technical manual of the equipment manufacturer. Use the cables from Biosense Webster, Inc. that are intended for use with the corresponding catheters made by the same company.

NOTE: A power of 50 Watt must not be exceeded during ablation. The power rating must be restricted to 50 Watt for high power generators. The ablation temperature must not exceed 60°C in order to ensure safe ablation with this product.

Disposal

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

Contraindications

The application of the Vanguard Ablation Catheter bi BWB/DS BWQ 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 an intracardiac patch or baffle
- Retrograde transaortic access for patients with an aortic valve prosthesis
- Patients who have shown sensitivity in the past 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
- Stroke
- Thrombosis and embolism
- Cardiac perforation
- Tamponade
- Heart valve injuries
- Arrhythmia
- Contact problems between the catheter and pacemaker
- Intermittent or complete failure of effective stimulation and/or sensing
- Loss in effectiveness of stimulation (exit block)
- Puncture of the subclavian artery
- Injury of the veins

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.

Adverse reactions

The following adverse reactions during catheter procedures are described in literature:

Pulmonary embolism, myocardial infarction, strokes, cardiac tamponade and death.

In relation to catheterisation and catheter procedures:

Vascular bleeding/local haematoma, thrombosis, AV fistulae, pseudoaneurysma, thromboembolism and vasovagal reactions, cardiac perforation, tamponade, thrombus, air embolism, arrhythmia and valve injuries, pneumothorax and haematothorax.

In relation to alternating currents:

Pain/discomfort in the chest, ventricular tachyarrhythmia, TIA, apoplectic stroke, total heart block, coronary artery spasm, coronary artery thrombosis, coronary artery transaction, cardiac thromboembolism, percarditis, cardiac perforation/tamponade, valve injury and increased phosphokinase values.