INSTRUCTIONS FOR USE

Vanguard Irrigated Ablation Catheter BW
Vanguard Irrigated Ablation Catheter uni BWG
Vanguard Irrigated Ablation Catheter SF uni BWR
Vanguard Irrigated Ablation Catheter bi BWH
Vanguard Irrigated Ablation Catheter SF bi BWS
Vanguard Irrigated Ablation Catheter NAV uni BWI
Vanguard Irrigated Ablation Catheter SF NAV uni BWT
Vanguard Irrigated Ablation Catheter NAV bi BWJ
Vanguard Irrigated Ablation Catheter SF NAV bi BWU

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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

Device information

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

VANGUARD assumes no liability for damages that arise from improper operation of the Vanguard Irrigated Ablation Catheter BW 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 fully remanufactured solely by VANGUARD AG, who markets the device without collaboration by Biosense Webster Inc. "Biosense Webster", “Carto”, “Thermocool”, “NAVISTAR” and "CELSIUS" are protected brands of the manufacturer of the original product Biosense Webster Inc., USA or one of its affiliated companies.

Packaging labelling and symbols

Content:
One (1) Vanguard Irrigated Ablation Catheter BW. The medical device may only be used until the specified "Expiry date" (⧗).

	For single use only
	Do not resterilise
	Do NOT use if the sterile packaging is damaged or has been opened
	Sterile, sterilization using ethylene oxide
	Expiry date
	Serial number
	Store protected from light
	Store in a dry place
	Information about acceptable ambient temperature during storage and transportation
	Read the instruction for use
CE 0086	CE mark with the identification number of the notified body
	Manufacturer

PRODUCT DESCRIPTION

The Vanguard Irrigated Ablation Catheter BW with or without navigation function is a catheter with four (non-SF type) or six (SF type) electrodes, a lumen 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. The catheter must be used with suitable introducers. Successful ablation requires the use of suitable equipment (e.g. generator, cable, irrigation pump and a reference electrode).

The head electrode of the catheter has several irrigation openings for irrigating and cooling with heparinised normal saline solution. Thereby a distinction is made between the two types non-SF (hole Ø 0.4 mm) and SF (hole Ø 0.09 mm). To irrigate with saline solution through the lumen of the catheter, a compatible irrigation pump must be connected to the proximal luer connection.

The Vanguard Irrigated Ablation Catheter BW is equipped with a torsion-resistant shaft, which permits the correct positioning of the instrument tip. The catheter tip can be bent and is brought into the required position via the curvature control unit at the handle. Vanguard Irrigated Ablation Catheters BW are available with uni- (bendable in one direction) or bi-directional (bendable in two directions) curvature adjustment (refer to section technical data). Starting from the catheter tip, there are three attached ring electrodes used for recording and stimulation purposes. Ring electrodes 5 and 6 (SF catheter only) are not used for stimulation or recording purposes. The tip electrode serves to transfer the HF current required for ablation. The catheter tip contains a sensor to measure the electrode temperature.

The catheter has to be used with suitable recording systems, generators and appropriate cables with suitable plug-in connections. Catheters with navigation function (NAV) are equipped with a magnet sensor next to the thermosensor in the catheter tip, which provides information about the position of the catheter tip. The location determination and the use of them is described in the user manual of the Carto®-System and requires additionally suitable reference systems.

For additional information on required accessories, e.g. generator, cable and irrigation pump, please refer to the respective instructions for use or user manual.

Intended use

The Vanguard Irrigated Ablation Catheter BW is intended for temporary intracardiac electrophysiological mapping (stimulation and recording) in conjunction with compatible connection cables from the Biosense Webster Inc. and suitable devices for electrophysiological mapping and when used with compatible radiofrequency generator, for cardiac ablation. All Vanguard Irrigated Ablation Catheter BW are intended for use with compatible HF generators, cables navigation systems, 8F introducer sheaths and irrigation pumps. It is recommended that dispersive electrodes meet or exceed the requirements according to EN 60601-2-2.

Catheter types with navigation function (see technical data) provides location information when used with a Carto® 3 EP Navigation System (version 2.3 or higher).

It is the responsibility of the physician to use an appropriate surgical procedure and technique. The procedure described in the instruction for use is only for information. Each physician must apply, supplement or adapt the information in the instruction 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 for catheters without navigation function

Shaft diameter:	7 F	
Usable length:	115 cm	
Head electrode diameter:	7 to 8 F	
Length of head electrode:	3.5 mm	
Sensors in catheter tip:	Temperature sensor	
Number of ring electrodes:	3 active, SF type also with 2 passive	
Diameter of ring electrodes:	7 to 8 F	
Distance between ring electrodes:	(2 – 5 – 2) mm	
Electrical connection:	10-pole (Redel PAA, female)	
Irrigation connection:	Luer ISO 5942 female, variant A	
Rated voltage:	220 V_P	
Irrigation hole:	non-SF type:	6 x 0.4 mm
	SF type:	56 x 0.09 mm

"Redel" is a registered, protected brand of INTERLEMO HOLDING S.A. (INTERLEMO HOLDING AG / INTERLEMO HOLDING LTD); Chemin des Champs Courbes 28, 1024 Ecublens, Switzerland (CH).

Vanguard Irrigated Ablation Catheter bi BWH / SF bi BWS

Item no.	34474	34830	34831	34842	34832	34472	34843
Corresponding REF-No. of original manufacturer	36Q35M	36Q55M	36Q5JM	BDI35BDRT	BDI35BFRT	BDI35DFRT	BDI35FJRT
Curvature type	D-F	F-F	F-J	B-D	B-F	D-F	F-J
SF type	Non-SF			SF			

Vanguard Irrigated Ablation Catheter uni BWG / SF uni BWR

Item no.	34827	34828	34475	34829	34837	34470	34838	34839
Corresponding REF-No. of original manufacturer	35Q13R	35Q33R	35Q53R	35Q73R	D131601	D131602	D131603	D131604
Curvature type	B	D	F	J	B	D	F	J
SF type	Non SF				SF			

Technical data for catheters with navigation function

Shaft diameter:	7.5 F
Usable length:	115 cm
Head electrode diameter:	8 F
Length of head electrode:	3.5 mm
Sensors in catheter tip:	Temperature sensor, magnetic sensor
Number of ring electrodes:	3 active, SF type also with 2 passive
Diameter of ring electrodes:	8 F
Distance between ring electrodes:	(2 – 5 – 2) mm
Electrical connection:	25 PIN (Hypertronics D02, female)
Irrigation connection:	Luer ISO 5942 female, Variant A
Rated voltage:	220 V_P
Irrigation hole:	non-SF type: 6 x 0.4 mm
	SF type: 56 x 0.09 mm

Vanguard Irrigated Ablation Catheter NAV bi BWJ / SF NAV bi BWU

Item no.	34758	34808	34805	34806	34844	34469	34807
Corresponding REF-No. of original manufacturer	36H35M	36H5JM	BNI35BDH	BNI35BFH	BNI35DDH	BNI35DFH	BNI35FJH
Curvature type	D-F	F-J	B-D	B-F	D-D	D-F	F-J
SF type	Non SF		SF				

Vanguard Irrigated Ablation Catheter NAV uni BWI / SF NAV uni BWT

Item no.	34833	34834	34473	34835	34836	34471	34840	34841
Corresponding REF-No. of original manufacturer	34H17M	34H27M	34H37M	34H57M	34HJ7M	D131802	D131803	D131804
Curvature type	B	C	D	F	J	D	F	J
SF type	Non SF					SF		

CE 0086 This product bears a CE mark in accordance with the requirements in the EC directive 93/42/EEC.

Compatible devices, accessories and settings

All Vanguard Irrigated Ablation Catheter BW should only be used with devices and accessories which are compatible with the corresponding catheters from the original manufacturer Biosense Webster. The manufacturer reference numbers of the corresponding original catheters are given above in the tables of technical data. If the catheter is connected to a HF generator which supports a HF output voltage of >220 V_P, the output voltage must be limited to 220 V_P.

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.

Proximal connector or handle or cable is in contact with liquid!

Impairment with the function of the catheter

→ Prevent the connector, the handle and the cable 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!

Impairment with electrical safety and function

→ Bring the catheter tip to a straight position with the curvature control and then pull them out and remove coagulation deposits from the tip (cleaning). Leave the electrode tip in a straight position when cleaning. Avoid rotating or scrubbing 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 power supply!

Hazard due to loss of function or loose tip electrode

Do not perform more than 30 ablations at a time with a power 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 drain, 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 power supply in the case that the power drain is too low.

→ The dispersive electrodes used should comply with or exceed 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!

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 HF 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 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.

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

Unclear risks and long-term risks

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

⚠ Sterilized 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 the package is 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/resterilization and reuse after intended use of the catheter by the user or operator!

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 HF 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 switch 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.

PRECAUTIONS

1. Monitoring of the tissue temperature is not possible with temperature sensors of the catheter. The temperature sensor implemented in the catheter measures the temperatures of the head electrode not the temperature in the interface of electrode/tissue and tissue. This temperature is displayed on the HF surgical unit. The temperature sensor is used to ensure the appropriate irrigation flow rate.

   A decrease of the electrode temperature shows, that the ablation electrode is irrigated with saline solution. Then the supply of the alternating current could start. The monitoring of the electrode temperature during the HF current flow ensures that the irrigation rate of saline solution is constant.
2. Comparative studies and animal testing have shown that, during the ablation, there was no significant increase in electrode temperature. The electrode temperature is not a measure for tissue heating caused by HF energy.
3. An overly rapid power increase during ablation may lead to perforation caused by the abrupt development of steam. The procedure for increasing the power is described in the instructions for use and must be followed.
4. If the catheter is accidentally passed through a patient’s prosthetic tricuspid valve, the

valve could be damaged.

5. The risk of perforation and/or pericardial effusion during the application of catheter systems is greater when a patient's prior ablation procedure(s) resulted in atrial flutters.
6. The patient's fluid balance must be monitored during the application of HF ablation in accordance with medical and clinical protocols. This measure serves to prevent fluid overload in a patient. Depending on the patient, complications may occur which could impair the ability to deal with fluid overload. If patients are affected, water retention and lung oedema or heart attacks may occur after finishing of the procedure. Older patients, patients with congestive cardiac insufficiency or renal insufficiency contain to the risk groups. The risk of fluid overload for the patient must be determined prior to application of the ablation procedure.
7. Intravenous heparin should be used if the catheter is introduced into the left side of the heart. This may prevent thromboembolisms. Clinical guidelines and general good practice should be applied for optimal anticoagulation after the procedure.
8. There is no evidence available for the safety of this catheter at electrode temperatures above 40°C. Therefore ensure that the CATHETER SELECTION BUTTON on the compatible RF generator is set to "Tcool SF" or to a THERMOCOOL SF option. Ensure that the maximum temperature of 40°C is not exceeded.
9. Take precautions to minimise collateral damages to neighbouring structures while performing ablations near anatomical structures.
10. To prevent injuries to the oesophagus, take precautions when performing ablations near the oesophagus (along the rear wall of the left atrium). The HF output should also be reduced accordingly.
11. Take precautions when performing ablations near the phrenic nerve to prevent its damage. The HF output and stimulation should also be reduced accordingly in order to determine the proximity of the ablation electrode(s) to the nerve.
12. The catheter may not be autoclaved.
13. Any kind of contact between the catheter and organic solvents (e.g. alcohol) is to be avoided.
14. The proximal handle and cable plug must be kept dry. Immersing these components may lead to impairments in the electrical line and must therefore be avoided.
15. The head electrode may not be impaired by cleaning, e.g. scrubbing or twisting.
16. The saline solution for irrigation may not contain air bubbles. This must be ensured before use. The presence of air bubbles in saline solution may cause embolisms.
17. The catheter and irrigation pipes must be irrigated with heparinised normal saline solution.
18. Before use, read and understand the respective instructions for use of the Vanguard Irrigation Ablation Catheter BW completely.
19. Ablations on the heart must be performed in a fully equipped electrophysiological laboratory and by appropriately trained personnel. Personnel must be trained in the use of the Vanguard Irrigation Ablation Catheter BW.

20. Based on electromagnetic compatibility requirements and other safety regulations in the clinics, electrophysiological catheters and systems may only be used in X-ray shielded rooms.
21. To insert or withdraw the catheter, the catheter tip must be set to straight. To insert or withdraw the catheter, the catheter tip must be set to straight by always moving the rocker lever (bi-directional curvature adjustment) or the thumb knob (uni-directional curvature adjustment) to the neutral position.
22. The Vanguard Irrigation Ablation Catheter BW may not be used without irrigation. To prevent coagulation in the lumen of the catheter, a steady infusion of heparinised normal saline solution must be maintained.
23. Neutral electrodes are recommended for application. These must comply with the requirements according to EN 60601-2-2. For neutral electrodes, follow the respective instructions for use.
24. Before using the product, thoroughly check the sterile packaging and the catheter for damages. Damages to the sterile packaging or to the catheter cannot be tolerated. Damaged products may not be used.
25. The Vanguard Irrigated Ablation Catheter BW is gas sterilized with ethylene oxide. The catheter can be used until the expiry date on the packaging label. Use of the catheter after the expiry data is prohibited.
26. The Vanguard Irrigated Ablation Catheter BW is a single-use product and intended for single patient use only.
27. The catheter may not be resterilised or reused.
28. To minimise the risk of tissue injury, the insertion of the catheter must be monitored fluoroscopically and by electrogram data.
29. MRI could shift the catheter or could lead to catheter heating and could result in distorting of the image. The Vanguard Irrigated Ablation Catheter BW must be kept away from MRI devices.
30. During the scope of HF surgical procedures, there is a risk of flammable gases and other materials igniting, which is why flammable materials may not be stored in the vicinity of HF surgical procedures. This requires separate precautions.
31. The use of Vanguard Irrigated Ablation Catheter BW in combination with suitable, compatible HF generators in normal operation creates electromagnetic interferences (EMI) which may negatively effect the function of other devices.
32. Before using the catheter, check the porosity of the holes by irrigating the catheter and all tubes with heparinised normal saline solution.
33. The user is responsible for regularly checks and has to test reusable cables and accessory parts.
34. Ablation on the septum side includes an increased risk for the patient for the appearance of a complete AV block. A complete AV block occurring in a patient treated with HF ablation requires the insertion of a permanent pacemaker.
35. Risks of myocardial infarctions exist due the placement of the catheter in the coronary vessels and/or during the HF ablation. To prevent the placement of the catheter in the

coronary vessels, a suitable fluoroscopic visualisation has to be applied at the access to the aorta.

36. In contrast to standard HF ablation catheters without irrigation, the Vanguard Irrigated Ablation Catheter BW creates larger lesions. Ablations near structural areas such as the sinu-atrial and atrioventricular nodes must therefore be performed with extreme caution.
37. The Vanguard Irrigated Ablation Catheter BW is intended for use in connection with compatible accessories (irrigation pump, HF surgical unit, Carto® EP system, cables, plug connectors). An appropriately compatible irrigation pump is recommended to ensure the correct irrigation rate.
38. When using electrophysiological catheters, the accuracy of temperature measurement basically depends on the HF surgical unit. This also applies to the Vanguard Irrigated Ablation Catheter BW. The user manuals of the respective devices contain information on the accuracy of temperature measurements.
39. If the output power is too low or the monitored impedance value is too high or if the device doesn't functioned with correct settings, the reasons therefore could be a wrong application of the neutral electrode or a faulty electrical connection. Before increase of power, it has to ensure that the electrical connection is free of failures and the neutral electrode is in correct use.
40. Ensure that you minimise X-radiation during the ablation procedure. Within the scope of ablation procedures with catheters, the X-radiation intensity and duration of fluoroscopic imaging can lead to a significant release of X-radiation. This creates an increased risk as a result of somatic and genetic effects on patients and laboratory personnel.
41. Minimise X-radiation during the procedure. During catheter ablation procedures, the intensity of X-radiation and the duration of fluoroscopic imaging may lead to considerable exposure to X-radiation. Only perform catheter ablations if radiation exposure has been taken into appropriate consideration and measures to minimise radiation have been taken. The use of this catheter on pregnant women has to be very carefully considered.
42. Electrodes and probes for monitoring and stimulation devices can emit high-frequency currents. To reduce the risk of burning, you should take electrodes and/or probes as far as practically possible from the place of ablation and neutral electrodes. Protective impedances may further reduce the risk of such burns. They also permit continuous monitoring of the electrocardiogram during energy output.

43. The temperature sensor located in the catheter tip only measures the temperature of the electrode tip. The catheter does not record the tissue temperature. This temperature is displayed on the HF surgical unit and only applies to the cooled electrode. If the temperature is not displayed on the HF surgical unit, check the wiring to the HF surgical unit. If the temperature is still not displayed, the temperature measurement system may be faulty. If these errors occur, they must be rectified before the output of HF energy.

44. The Vanguard Irrigated Ablation Catheter BW used in connection with a compatible HF generator can emit enormous electrical output. Both the catheter and the neutral electrodes must be handled correctly. In the event of non-compliance, the use of the catheter may lead to injury of the patient and/or operator. Under no circumstances may the patient be in contact with grounded metal objects during the course of energy output. If the temperature on the display of the HF surgical unit does not increase during ablation, switch off the power supply and check the settings.
45. Use the Vanguard Irrigated Ablation Catheter BW in connection with conventional systems (under X-ray/fluoroscopic control to determine the position of the catheter tip) or with the CARTO® EP navigation system extremely carefully to avoid injuries to the heart, tamponades or perforations. Advancing the catheter must follow not only under X-ray controlled conditions but also extremely carefully due to the tip's strength properties. Avoid excessive force when advancing or retracting the catheter.
46. If the limit value for the HF current is exceeded (rise in temperature or impedance), remove the catheter and clean the tip (e.g. of adherent coagulate). When cleaning the head electrode, ensure that its position is not twisted or changed. This ensures that the electrode is not loosened or damaged. Before reinserting the catheter, ensure that the irrigation holes of the head electrode are not blocked.
47. The applied HF current during ablation may cause implanted pacemakers and implantable cardioverter-defibrillators (ICD) to be impaired. To reduce the risk of undesired pacemaker function during ablation, the function of an external pacemaker and defibrillator, as well as the possibility of the pacemaker system's temporary programming to minimum output or system deactivation must be temporary available.

    During ablation, proceed with particular care if the procedure is performed in close proximity to permanent wires around the atrium or ventricle. During ablation, the ICD must be set to the OFF mode. After ablation, all patients must undergo complete analysis for implantable devices.
48. There is no evidence available for the following events:
    a) Risk upon termination of an anti-coagulation therapy after catheter ablation.

    → affected patients must be treated in accordance with the "ACC/AHA/ESC Guidelines for the Management of Patients in Atrial Fibrillation"

    b) The efficacy and safety of HF ablation treatment of atrial fibrillation in patients with severe left-ventricular dysfunction, progressive cardiac insufficiency, significant left atrial enlargement and illnesses concerning the structure of the heart.

    c) On the long-term risk of extended fluoroscopy and of HF-induced lesions.

    → application in prepubescent children should be carefully considered

    → the risk and benefit of the use of the catheter in asymptomatic patients were not investigated

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

Stored cool, dry and protected from light. Range of storage temperature is between 5°C and 25 °C.

→ Information about storage conditions is also 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 custom-designed 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 grounded sufficiently and centrally.
- It is a requirement for intracardiac potential recording and/or stimulation that medical professionals are trained sufficiently and that a fully equipped electrophysiology laboratory is present. The procedure itself may only be carried out by a trained, 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 product for the procedure is to be used.

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

→ 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.

→ Submit the irrigation connection and the irrigation holes on the head electrode 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 vessel through which you can push the catheter in.
- → Connect the catheter to a suitable HF surgical unit and/or generator and the recording unit using the appropriate cables. Catheters with navigation function will be connected like described in the user manual of the Carto® system.
- → Connect a suitable irrigation pump to a bag of heparinised normal saline solution (1IU heparin/ml) and use it to fill the irrigation tube. The irrigation tube may not contain air bubbles once the shut-off valve is closed.
- → Insert the irrigation tube into the pumps and irrigate until the air escapes from the open end of the tube.
- → Connect the catheter to the irrigation pump or the irrigation tube respectively.
- → Using X-ray control and electrocardiogram as guidance, insert and push the catheter forward and position it in the required place in the endocardium.

NOTE: To simplify positioning of the catheter tip from catheters with bi-directional curvature adjustment, you can bend it using the curvature control unit (rocker lever and locking screw). By activating the rocker lever to one side, the catheter tip is also bent to that side. The position of the rocker lever determines the curvature of the tip. The catheter is straight and can be inserted or retracted when the rocker lever is in neutral position. Curvature mobility is adjusted via the locking screw. Mobility can be reduced by turning the locking screw in clockwise direction and increased by turning it in anti-clockwise direction.

NOTE: To simplify positioning of the catheter tip from catheters with uni-directional curvature adjustment, you can bend it using the curvature control unit (thumb switch) on the handle. The catheter tip is bent by pushing the thumb switch in distal direction. The position of the thumb switch determines the curvature of the tip. The catheter is straight and can be inserted or retracted when the thumb switch is in neutral position (proximal end position).

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: In order to perform ablation under HF current, a secure connection of the catheter and the HF generator is necessary. Use only the connection cable from the Biosense Webster Inc. and also read the user manual of the HF generator.

NOTE: To close the electric circuit, the neutral electrode must be connected to the reference electrode input of the HF generator. Prior to ablation, the circuit impedance should be within the range of standard values for ablation. The HF 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 supply of HF 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 generator's automatic deactivation. In this case, the catheter must be removed in order to clean the electrode. In this regard, use sterile saline solution. You can also use a sterile swab. Carefully clean just the tip and do not rub, twist or bend it to avoid damaging or loosening the tip. Please also read the sections "Safety instructions" and Precautions". Before continuing with surgery, ensure that the irrigation system (catheter and irrigation tubes) are free of trapped air and that irrigation is functional.

NOTE: For irrigation, use heparinised (1 IU heparin/ml) normal saline solution at room temperature. Trapped air in the irrigation system (catheter and irrigation tubes) must be removed by irrigating. Ensure that all irrigation holes are unblocked.

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 user manual of the equipment manufacturer. Use the cables supplied by Biosense Webster Inc. that are intended for use with the corresponding catheters made by the same company.

NOTE: A power output of 50 Watt must not be exceeded during ablation, if the catheter is in parallel alignment to the tissue. If the catheter is vertically aligned with the tissue, a power output of 35 Watt may not be exceeded. Generators with higher output values must be limited to the appropriate maximum output. The temperature of the head electrode may not exceed 40°C to ensure safe ablation with this product. Temperature and impedance must be monitored on the HF surgical unit during ablation.

NOTE: Apply a continuous irrigation flow rate of 2 ml/min. During ablation with the use of a Stockert HF generator, apply the irrigation flows listed in the table below. It is recommended to irrigate with the higher flow rate 5 seconds before and after ablation.

Catheter type	***non-SF***		***SF***	
Ablation	***atrial***	***ventricular***	***atrial***	***ventricular***
Power interval	15 W to 30 W*	31 W to 50 W	15 W to 30 W*	31 W to 50 W
Flow rate	17 ml/min	30 ml/min	8 ml/min	15 ml/min
Application period	30 to 120s	60 to 120s	30 to 120s	60 to 120s

*Working above 30 W is possible if no transmural lesions are created at lower output rates. For outputs > 30 W, the irrigation flow rate must be 15 ml/min.

NOTE: Start the ablation at 15-20 W and iteratively increase by 5-10 W after 15 seconds, until a transmural lesion is reached. Transmural lesions are characterised by an 80% reduction in unipolar atrial electrogram amplitude or by the occurrence of double potential at equal or lower amplitudes.

NOTE: Ablation may not commence before the head electrode temperature has decreased by at least 2°C and has therefore confirmed the higher flow. Monitor the temperature of the tip during ablation and ensure correct irrigation. The displayed temperature is that of the head electrode and not that of the tissue.

NOTE: During ablation of isthmus-dependent flutters it is recommended to only exceed the output of 30 W (max. 50 W) once no conduction block is achieved with outputs < 30 W.

Disposal

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

Contraindications

The use of the Vanguard Irrigation Ablation Catheter BW is contraindicated for:

- patients with an intracardiac parietal thrombus
- patients who have undergone a ventriculotomy or atriotomy in the preceding eight weeks
- patients with heart valve prosthesis
- transseptal access in patients with interatrial patch or baffle
- patients with myxoma or intracardial clots
- in coronary vessels
- 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
- 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 the event of known side effects, please also refer to appropriate expert 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, pseudoaneurysm, thromboembolism and vasovagal reactions, cardiac perforation, pericardial effusion/tamponade, thrombi, air embolism, arrhythmia and valve injuries, pneumothorax and haematothorax, water retention and lung oedema, hypoxia, pleural effusion, Acute Respiratory Distress Syndrome (ARDS), congestive cardiac insufficiency, aspiration pneumonia, pneumonia, asthma attacks, hypotension, malfunction of the implantable Cardioverter Defibrillator (ICD), anaemia, thrombocytopaenia, disseminated intravascular coagulation, haemorrhagic areas, systemic infections, urinary tract infections, apnoea caused by sedation, CO2 retention caused by sedation with lethargy and cholecystitis.

In relation to alternating currents:

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

Without reference to the device or procedure:

Urine retention, transient numbness of the limbs, Parkinson’s disease and gastrointestinal haemorrhages.