VEGA

IMPLANT MANUAL

MicroPort

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1. GENERAL DESCRIPTION

The VEGA lead is a bipolar, endocardial, steroid-eluting, silicone-insulated lead with Silglide® surface treatment to improve the lead's gliding properties. It is an active fixation lead with an extendable/retractable fixation helix for permanent pacing and sensing of either the atrium or ventricle. The lead is designed to be used with implantable cardiac pacemakers and defibrillators.

Please refer to the pulse generator device MRI Solutions Manual for the complete list of MRI conditional combinations.

All materials used in the manufacture of MicroPort leads have been submitted to strict tests and are perfectly biocompatible.

In this steroid-eluting lead, a silicone elastomer collar containing 310 µg of Dexamethasone Sodium Phosphate (DSP) is located just behind the electrode tip

Upon exposure to body fluids, the steroid elutes progressively into the cardiac tissue around the electrode.

The steroid aims to minimize the inflammatory response and reduce threshold elevation during the first weeks post-implantation.

VEGA's 2 mm lead body requires a 7F (2.33 mm) introducer sheath

See the technical specifications relevant to the model of lead in chapter 11 of this manual.

. INTENDED USE AND INDICATIONS

VEGA leads are active straight leads indicated for anti-brady therapy according to applicable guidelines, and can be used in the ventricle or atrium. VEGA leads, when connected to a pacemaker/defibrillator are intended to sense the heart activity or pace the heart with electrical impulses if needed, as indicated in the guidelines on cardiac pacing in order to maintain or restore a normal heart rate.

VEGA leads R45, R52 and R58 are suitable for MRI (allowing patients to safely undergo an MRI examination) with a MicroPort MR Conditional pulse generator device.

Refer to the pulse generator device MRI Solutions Manual available on the website www.microportmanuals.com for the complete MRI checklist prior to MRI examination.

The VEGA re-intervention kit is intended to be used with the VEGA leads family only and provides additional accessories at implant or re-intervention:

— The fixation tool (also called “butterfly tool”) is intended to extend/retract the helical screw of the lead.

— The vein lifter, to aid venous insertion of the lead.

— The funnel, to facilitate stylet insertion into IS-1 lead connector.

— The stylet, to provide additional stiffness and controlled flexibility for manoeuvring the lead into position. It provides an aid for stiffening the lead and allowing lead insertion into the vein, lead advancement through the vessels and lead positioning at the implant site inside the heart chamber.

. CONTRAINDICATIONS

Implantation of endocardial leads is generally contraindicated in patients with mechanical tricuspid valves.

Do not implant in patients for whom a single dose of 310 µg of dexamethasone sodium phosphate may be contraindicated.

. WARNINGS

External defibrillator

During any implantation/explantation procedure, an external defibrillator must be kept at hand in case of emergency.

Handling the lead and stylets

— Never bend, twist or strain the pacing lead while maneuvering it, using excessive force may permanently damage the device.

— Avoid grasping the lead with surgical instruments as this may cause arrhythmias or damage the lead.

— Protect the electrodes from contact with powders, fibers and silicone oil lubricants. They may contaminate the electrodes and therefore reduce electrical performances.

— Do not immerse the lead tip in fluid prior to implantation as this may cause elution of some of the steroid and reduce the anti-inflammatory effect.

— Keep gloves free of blood and body fluids while manipulating the stylet to minimize friction between the stylet and the lead lumen.

— Do not attempt to curve the stylet when it is in the lead.

— Do not attempt to alter the lead in any way.

— Use only the appropriate stylets provided by the manufacturer.

— Repositioning or removing a lead may be difficult due to growth of fibrous tissue.

Electrical environment

— lectrosurgical units (e.g. electrocautery) should not be used near an active implantable device or its associated leads as this may cause electrical interference. Currents generated from electrosurgical devices may cause permanent loss of output, induce ventricular fibrillation, or reset programmed parameters in the active implantable device. If using electrocautery is unavoidable, however, program the therapy parameters to “Off” and be sure the electrocautery discharge does not make direct contact with the active implantable device or leads. Following electrocautery, determine the functional integrity of the circuitry and programming.

— When implanted, the lead is in direct electrical contact with the myocardium. Only battery-operated and CF class powered electrical appliances should be used during the procedure.

— An AC electrical appliance should not be placed in the vicinity of the patient, as it could be accidentally connected to the lead.

— All operating room electrical appliances must be properly grounded.

Electrocoagulation

It is strongly advised not to use electrocoagulation appliances in the vicinity of an implanted lead.

Pacing system

The use of the pacing system (MicroPort MR Conditional pulse generator and VEGA leads R45, R52 and R58) is suitable for MRI under strict conditions.

NOTE: Refer to the pulse generator MRI Solutions Manual available on the website www.microportmanuals.com for the complete MRI checklist prior to MRI examination.

. CLINICAL TRIAL INFORMATION

.1. VEGA PRE-MARKET CLINICAL DATA

Clinical data supporting the VEGA leads was obtained on a similar lead, Beflex RF. The only difference between the VEGA leads and the Beflex RF leads is the addition of a lubricious outer coating intended to improve handling during implant. A risk assessment and non-clinical verifications and validations determined that the coating did not impact lead safety or performance. The Beflex RF leads are not available in the U S. but are sold in urope and other out of US markets since 2 12. Clinical data for the Beflex RF leads was obtained in the PLEASUR -S pre-market clinical trial.

The initial phase of PLEASURE-S was a non-randomized, prospective trial which studied 203 Beflex RF leads, models RF46D and RF45D. The study was designed to demonstrate with 95% confidence that the proportion of subjects free from lead complication (serious device-related adverse effect) is greater than 90%. Setting the Type 1 error to 5%, the statistical power to 80%, the one-sided test-expected rate success to 97% and using “proc power” of SAS 9.1, the sample size required was 89.

203 Beflex leads were implanted in 123 patients at 18 centers located in France, Spain and Germany, in either or both the atrial (98) and ventricular (105) chambers. The study evaluated the safety and performance of the leads by:

1. (Safety) Demonstrating the absence of excessive risks related to the lead or its use, when used in accordance with the lead’s manual/instructions for use (IFU).
2. (Performance) Demonstrating that (assuming the IFU is followed) the device meets expectations regarding electrical performance.

Primary objective and results:

The primary (safety) objective was to assess the complication rate per lead model with a confidence interval, and also measure the rate of other adverse events. There were two (2) lead complications recorded in two (2) patients with atrial implants, resulting in a 98% rate of patients free of lead complications at 3 months. The lower 95% confidence bound was 93.7% (p=0.002). In the ventricle, four (4) lead complications occurred in separate patients, resulting in a rate of 96.2% of patients free of lead complications at 3 months. The lower confidence bound was 91.5% (p=0.0167).

A second study phase was added to gather additional data on ventricular implants. Fifty-one (51) additional patients were implanted with ventricular leads and followed for 3 months. Within this group, two (2) lead complications occurred in two patients, resulting in cumulative safety results of 96.3% rate of patients free of lead complications at 3 months. The lower 95% confidence bound was 92.1% (p=0.002).

.2. SECONDARY ENDPOINTS

Secondary Endpoint #1 - Electrical performance:

The secondary (performance) objective was to document the pacing threshold, sensing amplitudes and impedance at implant, one month and three month follow up visits, as well as document the stimulation threshold at 3 months.

Electrical performance data is shown in the table below.

PLEASURE-S (Beflex clinical study) ELECTRICAL PERFORMANCE DATA								
Implanted lead		254						
Placement		98 (RA) / 156 (RV)						
Pacing threshold and pulsewidth	**lace-ment**	**Accep-tance criteria at im-plant**	**Month**					
			0		**1**		**3**	
			Pacing thresh-old	**ulse width**	**Pacing thresh-old**	**ulse width**	**Pacing thresh-old**	**ulse width**
	RA	< 1.5V	61±0.52V (n=81)	48 ±0.04ms	65±0.22V (n=88)	49 ±0.04ms	78±0.5V (n=89)	49 ±0.04ms
	RV phase 1	< 1.0V	49±0.14V (n=98)	48 ±0.06ms	78±0.47 (n=99)	49 ±0.03ms	78±0.26V (n=97)	51 ±0.04ms
	RV phase 2		5±0.3V (n=351)	50 ±0.00ms	8±0.3V (n=47)	49 ±0.03ms	9±0.4V (n=46)	49 ±0.03ms
Sensing threshold	**lace-ment**	**Accep-tance criteria at im-plant**	**Month**					
			0		**1**		**3**	
	RA	> 2.0mV	3.61±1.77mV (n=83)		3 74±1.85mV (n=89)		3.91±1.86mV (n=87)	
	RV phase 1	> 5.0mV	11.63±3.75mV (n=96)		12.03±3.93mV (n=95)		12.3±3.7mV (n=93)	
	RV phase 2		11.4±3.8mV (n=33)		11.1±4.0mV (n=46)		11.5±3.5mV (n=46)	
Impedance	**lacement**		**Month**					
			0		**1**		**3**	
	RA		588±148W (n=88)		532±95W (n=93)		550±97W (n=94)	
	RV phase 1		721±184W (n=99)		651±158W (n=99)		669±193W (n=100)	
	RV phase 2		735±141W (n=35)		614±116W (n=49)		645±117W (n=47)	

Secondary Endpoint # – Lead handling:

An additional endpoint was to obtain a subjective investigator assessment of lead handling characteristics. Investigators were asked to rate the leads on 16 technical characteristics related to performance with introducer/guidewire/stylet, ease of placement and visibility on Xray, compared with similar competitive leads. Ratings were obtained separately for atrial and ventricular implants.

Secondary Endpoint # – Adverse Events:

The final endpoint was to determine the incidence rate of all other adverse events, excluding complications (serious device related adverse effects) captured in Endpoint 1 but including observations (non-serious device related adverse effects), serious non device related adverse effects, mortality and unanticipated device effects. These were determined and reported descriptively by the investigators. A total of sixty nine (69) adverse events occurred during the two study phases. There was one (1) death that was not related to the device or procedure. The other sixty eight (68) events include three (3) lead-related observations, twenty five (25) procedure-related events and forty (40) neither lead nor procedure-related events.

SUMMARY OF RESULTS FOR SECONDARY ENDPOINTS:

#1 – Electrical Performance: Electrical performances were stable and as expected in both heart chambers, and the overall rate of observations/non-device related adverse events was also comparable to performance of predecessor leads.

#2 - Lead handling: Investigators ranked the mechanical handling of the Beflex lead as equal to competitive leads in both heart chambers. Therefore, the PLEASUR S Study demonstrated that at 3 months post-implant, the Beflex lead is safe and effective for its intended use in both the atrium and ventricle.

#3 – Adverse Events: Of the 98 leads implanted in the atrium, 98% were free of lead complications (serious device-related adverse effects) at 3 months. Of the 156 leads implanted in the ventricle, 96.3% were free of lead complications (serious device related adverse effects) at 3 months. These results are within expected performance range, based on historical performance of similar pacing leads.

. CONTENTS OF THE PACKAGE

.1. STERILE PACKAGE

— 1 Lead with suture sleeve and funnel pre-mounted
— 1 Vein lifter
— 2 Fixation tools
— Stylets (see table)

VEGA R45	VEGA R52	VEGA R58
2 Soft straight stylets: tapered, Ø 0.35 mm, green handle (one already pre-inserted into the lead)		
1 Firm straight stylets: tapered, Ø 0.40 mm, red handle		
1 Soft J stylet: open J curve, tapered, Ø 0.35 mm, light green handle and white cap		Not available on R58 model
1 Soft J stylet: close J curve, tapered, Ø 0.35 mm, green handle and white cap		
1 Medium J stylet: open J curve, non tapered, Ø 0.35 mm, blue handle and white cap		

NOTE: The packaged contents have been sterilized with thylene Oxide (EO). They are for single use only.

.2. NON-STERILE DOCUMENTATION

— Information leaflet
— Identification stickers

7. STORAGE AND USE

The lead must be stored at a temperature between 5°C and 25°C (excursion permitted within the range 0-50°C).

This lead is for single use only. Do not implant an explanted lead in another patient.

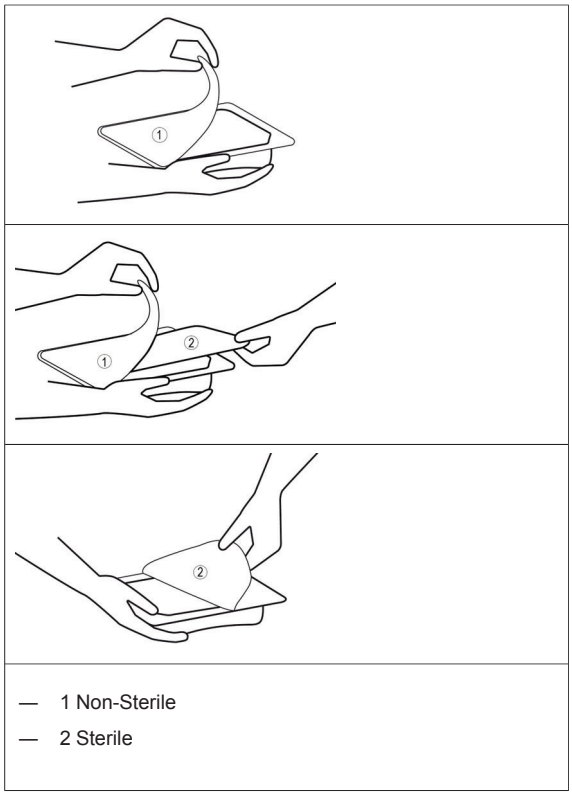
8. OPENING THE PACKAGE

Carefully examine the package before opening to:

— Check the "Use by" date. Do not use the product if the date has expired.

— Make sure that the package has not been damaged or opened. Do not implant the leads if sterility is compromised, or if there is physical damage to the product.

Open the sterile package within the sterile field and carefully remove the lead and accessories (see *Figure - Opening the sterile package*).



— 1 Non-Sterile

— 2 Sterile

Figure - Opening the sterile package

9. STERILIZATION

All MicroPort leads are sterilized with Ethylene Oxide (EO) before delivery.

In the event of an expired “Use by” date or alteration of the sterile package, DO NOT use the lead. Please contact your local MicroPort representative.

CAUTION: Never resterilize this lead.

10. OSSIBLE COMPLICATIONS

Events	Possible adverse effects
Lead displacement, conductor fracture	Intermittent or continuous loss of pacing and/or sensing
Rupture of insulation or helix electrode fracture	Pectoral stimulation, sudden fall in impedance, loss of efficacy of pacing, battery depletion
Cardiac perforation	Intermittent or continuous loss of pacing and/or sensing Muscle or phrenic stimulation Tamponade
Threshold elevation	Loss of capture
Poor lead/pacemaker or defibrillator connection	Intermittent or continuous loss of pacing and/or sensing Pectoral stimulation
Arrhythmia at implantation	Extrasystoles, tachycardia, ventricular/atrial fibrillation
Introduction of air (with subclavian approach)	Air embolism
Clotting defect	Hematoma
Myocardial trauma	Chest pain
Contamination	Pocket infection, septicemia

11. IMPLANT PROCEDURE

CAUTION:
Do not handle the lead with any surgical instruments as this may damage the lead.

11.1. VERIFYING MECHANICAL OPERATION

Prior to implantation, verify mechanical operation of the helix by extending and retracting it. To do this, clip the fixation tool onto the distal pin of the IS-1 connector (see *Figure - Placement of the fixation tool*). Turn the fixation tool clockwise (see number of turns according to models in *Table - Maximum number of turns*) while keeping the IS-1 connector to extend the screw (see *Figure - Rotation of the fixation tool*) and counterclockwise to retract it.

WARNING: In order to avoid overstress on the retractable mechanism prior to implant, it is recommended not to exceed the number of turns specified in *Table - Maximum number of turns* to test the screw exit on table. The maximum length of the extended screw is 1.5 mm.

	Number of turns	
Models	Straight stylet	J-Stylet
VEGA R45	8	14
VEGA R52	9	15
VEGA R58	10	16

Table - Maximum number of turns

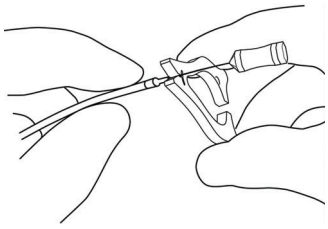


Figure - Placement of the fixation tool

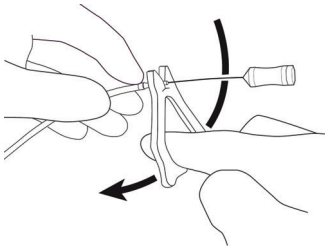


Figure - Rotation of the fixation tool

11.2. PREPARATION OF THE LEAD

To facilitate the movement through the veins the lead has a straight soft stylet pre-inserted. A funnel is also available to facilitate the exchange of stylet insertion into the lead (see *Figure - Introducing the stylet into the lead*).

WARNING: The product was designed and tested to give the best results using the stylets included in the lead package or the stylets included in the stylet kit of this product.

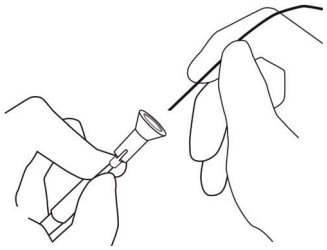


Figure - Introducing the stylet into the lead

1. Introduce the lead into the vein by using either a cutdown procedure or the percutaneous approach (Seldinger technique). The physician should determine the approach based on his or her preferred practice and patient anatomy. The vein lifter supplied can be used to simplify insertion of the lead into the vein.
2. Verify the lead advancement under fluoroscopy vigilance.

11.3. LEAD IMPLANTATION AND PLACEMENT

In the atrium

1. Insert the straight stylet up to the tip of the lead and introduce the lead into the vein.
2. When the lead is situated in the atrium, replace the straight stylet by a J stylet to reinforce the J of the lead and to facilitate handling.
3. Position the lead tip against the endocardium at the required site.
4. Position the lead by turning the stylet handle. When the lead lies perpendicular to the wall, advance the stylet until resistance is felt.

WARNING: Take care to avoid perforation of the endocardium.

5. Perform a preliminary threshold test by clipping alligator clips onto the IS-1 connector.
6. Clip the fixation tool onto the distal connector (see *Figure - Placement of the fixation tool*).
7. Press gently the lead tip against the endocardium using stylet.
8. Turn the fixation tool clockwise (see numbers of turns according models in *Table - Maximum number of turns*) to simultaneously extend the helix and affix it into the endocardium.
9. Confirm radiologically that the screw is extended (see *Figure - Retracted and Extended screw*).
10. Pull gently on the lead to verify that the screw is properly secured in the endocardium.

In the ventricle

1. Insert the straight stylet up to the tip of the lead and introduce the lead into the vein.
2. When the lead has penetrated into the middle of the atrium, withdraw the straight stylet by 10 to 15 centimeters.
3. Advance the lead to form a loop in order to negotiate the tricuspid valve.
4. When the loop is in the right ventricle, withdraw the lead while gently advancing the stylet. The tip of the lead straightens and advances towards the desirable site of the ventricle.

5. Advance the stylet completely and then all of the lead until the desirable site of the right ventricle is reached (apex or septum). Depending on the patient anatomy the apex should be avoided if there is an unusually thin wall.

If this procedure doesn't work:

1. Bend the stylet into a large J shape over the last 10-12 centimeters and try to negotiate the tricuspid valve directly. The tip of the lead then tends to ascend towards the pulmonary artery.
2. Replace the stylet with the straight stylet.
3. Slightly withdraw the lead which descends towards the apex of the right ventricle.
4. Position the lead tip against the endocardium at the required site.
5. Position the lead by turning the stylet handle. When the lead lies perpendicular to the ventricular wall, advance the stylet gently until resistance is felt.

WARNING: Take care to avoid perforation of the endocardium.

6. Perform a preliminary threshold test by clipping alligator clips onto the IS-1 connector.
7. Clip the fixation tool onto the distal connector (see *Figure - Placement of the fixation tool*).
8. Press the lead tip gently against the endocardium using the stylet.

WARNING: Take care to avoid perforation of the endocardium.

9. Turn the fixation tool clockwise (see number of turns according to models in *Table - Maximum number of turns*) to simultaneously extend the helix and affix it into the endocardium.
10. Confirm radiologically that the screw is extended (see *Figure - Retracted and Extended screw*).

Figure - Retracted and Extended screw

11.4. LEAD REPOSITIONING

If it is necessary to reposition the lead, insert the appropriate straight stylet into the lead before removing it.

Attach the fixation tool to the pin and rotate counter-clockwise with the number of turns according to *Table - Maximum number of turns* or until the screw has been retracted as confirmed through radiology (see *Figure - Extended and Retracted Screw*). Then, refer to the "Lead implantation and positioning" section to reposition the lead correctly.

11.5. ELECTRICAL MEASUREMENTS

Optimal pacing is achieved when the electrode is correctly positioned in direct contact with the endocardium.

This is verified by performing electrical measurements with the stylet completely withdrawn:

1. High energy test (10 V) to confirm the absence of phrenic nerve stimulation.
2. Measure the pacing threshold.
3. Record the intracardiac signal.
4. Measure the impedance at 5 V (0.5 ms); typical values are between 250 and 2 Ohms.

The pacing threshold must be measured with a battery-operated external cardiac pulse generator (follow the manufacturer's instructions for this device).

The following values should be obtained at the time of implantation (for a lead impedance of 500 Ohms and a duration of 0.5 ms):

Ventricle	< 1.0 V or < 2 mA	> 5.0 mV
Atrium	< 1.5 V or < 3 mA	> 2.0 mV

If the values indicated in the table above are not obtained, an alternate lead placement should be considered.

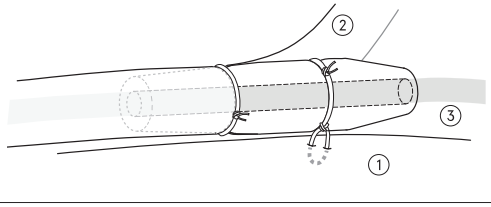
11.6. CONNECTIONS

MicroPort VEGA leads comply with International Standard IS-1 and can be adapted to all pacemakers or defibrillators with IS-1 connectors.

Follow the instructions provided with the pulse generator with regard to connection.

11.7. LIGATURE

To prevent displacement of the electrode, it is recommended to ligate the suture sleeve of the lead where it penetrates into the vein (*Figure - Ligature*).



— 1 Fascia
— 2 Vein
— 3 Lead body

Figure - Ligature

NOTE: Do not ligate directly onto the insulating material of the lead, which could cause rupture of the insulation, leading to ineffective pacing.

CAUTION: Leave a sufficient length when implanting the lead to allow for extension related to respiratory movements and cardiac contractions.

CAUTION: Do not secure the lead too tightly. Tight sutures may damage the lead.

12. EXPLANTATION

Lead extraction carries clinical risks and should be carefully assessed against leaving the lead in place, depending on the patient clinical situation and anatomy. When a lead extraction is required, proceed with great care[1]

An explanted lead must not be reused in another patient.

The explanted lead must be disposed of as medical waste according to applicable local regulations. You shall return the explanted leads to MicroPort CRM for disposal, carefully cleaned of all traces of contamination with disinfectant, and placed in a protective cover.

If it is necessary to abandon the lead, cap its connector pin. An abandoned lead should be capped so that the lead does not transmit electrical signals.

[1]Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. Heart Rhythm 6(7):1085-104, 2009

13. TECHNICAL CHARACTERISTICS

Models			VEGA R45	VEGA R52	VEGA R58
Length			45 cm	52 cm	58 cm
MRI compatibility			MRI conditional		
Connector	Type		IS-1 BI		
	Serial number identification		45DRG	52DRG	58DRG
Fixation	Screw mechanism		Retractable Screw		
			Pin driven		
	Screw length		1 5 mm		
	X ray markers		Yes		
	Number of turns to fully extend/retract the screw	Straight Stylet	8	9	1
		J-Stylet	14	15	16
Introducer	1 lead		7 F		
	1 lead + guidewire		9 5 F		
Distal electrode	Shape		Active screw		
	Material		Pt / Ir + TiN coating		
	Pacing surface		4 mm²		
	Steroid		310 µg of DSP*		
Proximal electrode	Material		Pt / Ir		
	Surface		44 mm²		
	Inter electrode distance		1 mm		
Lead body	Diameter		6 Fr (2 mm)		
	Insulation		Silicone tubing with Silglide® surface treatment		
	Conductors		MP35N		
	Internal coil		4 wires (max resistance 50 Ohms)		
	External coil		4 wires (max resistance 100 Ohms)		
Connector sleeve			Silicone		
Suture sleeve			Silicone		
Screw			Platinium-Iridium (Pt/Ir) alloy, Titanium nitride (TiN) coating		
Sensing Impedance			According to EN45502-2-1 standard: from 700 to 1300 Ohms		
Pacing impedance			According to EN45502-2-1 standard: from 700 to 1300 Ohms		

* *Dexamethasone Sodium Phosphate*

14. LIMITATIONS OF WARRANTY

MicroPort CRM S.r.l. (identified as “MicroPort” hereafter) pays the utmost attention to the manufacturing of its cardiac leads and the related accessories.

As these are to be implanted in the human body, which is a very hostile environment to all implantations, the leads and accessories manufactured and/or commercialized by MicroPort accordingly do not have any implicit or explicit warranty.

MicroPort will in no case be held responsible for any expenses whatever the nature or damages directly or indirectly resulting from the acquisition use, implantation, explantation or replacement of the leads or related accessories.

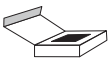
15. ATENTS

The VEGA lead described in this manual is covered by the following US patents:

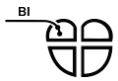
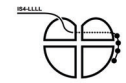
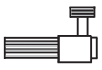
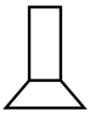
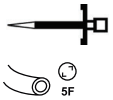
US5454838, US5496351, US5609612, US5693075.

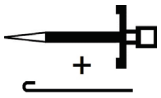
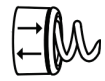
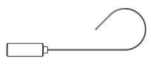
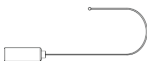
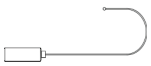
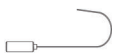
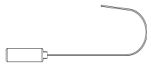
16. EXPLANATION OF SYMBOLS

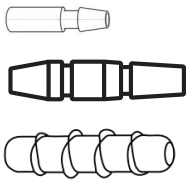
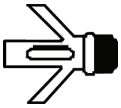
The symbols on leads package labeling have the following meaning (where applicable):

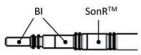
General symbols	Explanation of symbols
	Use by
	Date of manufacture
	Manufacturer
	Catalogue number
	Serial number
	European Representative
	Implantable device
	Medical Device
	Double entry package with external single sterile barrier system
	Packaging contents
	Sterile package contents
	Open here
	Do not use if the package is damaged

General symbols	Explanation of symbols
	Do not reuse
	Do not resterilize
	Sterilised using ethylene oxide
	Non sterile
	Temperature limitation
	MRI conditional
	Consult instructions for use
	Instructions for use in the CD-ROM
	This icon is used to call your attention to a particularly important point.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

Leads symbols	Explanation of symbols
	Bipolar lead - Atrial / Ventricular
	Bipolar lead - Atrial
	Bipolar lead - Ventricular
	Quadripolar lead - Left Ventricle
	Single coil bipolar defibrillation lead - ventricular
	Dual coil bipolar defibrillation lead – ventricular
	Fixation tool
DSP	Dexamethasone Sodium Phosphate
	Electrode spacing
	Endocardial, active fixation lead with protected fixed screw (SonRtip™ only)
	Fixture
	Fixture crank
 	Funnel
	Lead introducer

Leads symbols	Explanation of symbols
	Outer diameter
	Introducer with guidewire
	Lead
	LV lead S shape
	LV lead U shape
	LV straight tip
OUTER INSULATION	Outer insulation
	PSA Adaptator
Rx	By prescription only
	Retractable screw
	Store in a cool, dark, dry place
	Closed J stylet
	J stylet tapered, long tip
	J stylet tapered, short tip
	Open J stylet
	J stylet non tapered, "open J"
	Straight stylet tapered
	Stylet

Leads symbols	Explanation of symbols
	Suture sleeve
	Tined flange
TIP COATING	Tip coating
TIP ELECTRODE SURFACE AREA	Tip electrode surface area
TIP MATERIAL	Tip material
	Total length
	Torquer

Leads symbols	Explanation of symbols
	Tripolar connector featuring bipolar pacing/sensing and SonR™ sensor function (SonRtip™ only)
	IS4-LLLL Quadripolar Connector (low voltage, low voltage, low voltage, low voltage)
	DF4-LLHO Quadripolar Connector (low voltage, low voltage, high voltage, no connection)
	DF4-LLHH Quadripolar Connector (low voltage, low voltage, high voltage, high voltage)
	Vein lifter

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ALIZEA CELEA

MRI SOLUTIONS

Addendum to the ALIZEA and CELEA implant manuals

MicroPort

Intended audience

This manual is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Training for users

The following instructions for use are for informational purpose only. Each medical professional is responsible for their medical training and experience and should apply the following instructions according to the best clinical practices and patient condition.

TABLE OF CONTENTS

1. GENERAL DESCRIPTION

This MRI Solutions manual concerns ALIZEA and CELEA (SR and DR), and they will be hereinafter called "MR Conditional Devices". This manual is an addendum to their device manuals and provides important information about conditions for use and contraindications of examination using Magnetic Resonance Imaging (MRI) of patients implanted with a pacemaker system. It is designed for cardiologists, physiologists or other healthcare professionals programming the MR Conditional Devices, as well as for radiologists, technologists or other healthcare professionals performing the MRI scan.

NOTE: Refer to the device manual for the complete instructions for use available at www.microportmanuals.com.

The following symbols are related to the MRI environment. They are used to indicate the safety of devices and components in the MRI environment.

	**MR Safe Symbol**: A medical device which can safely remain with the patient during an MRI scan without conditions and in any MRI environment.
	**MR Conditional Symbol**: A medical device which can safely remain with the patient during an MRI scan under specific MRI conditions for use.
	**MR Unsafe Symbol**: A medical device known to pose hazards in all MRI environments. The Microport Programmer is MR Unsafe.

When implanted in combination with MR Conditional leads (listed below in "Overview of the MR Conditional products" section), the MR Conditional Devices constitute a Full Body MR Conditional pacing system. It is designed to allow patients to safely undergo an MRI scan, when used according to specific MRI conditions for use.

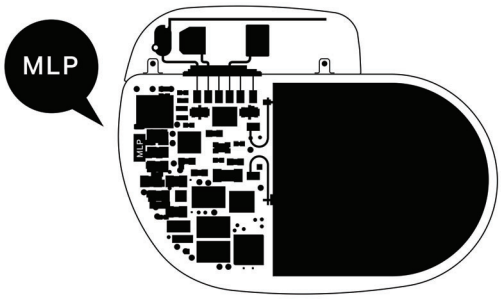
2. OVERVIEW OF THE MR CONDITIONAL RODUCTS

The MR Conditional Devices can be identified by the presence of letters in the device serial number, or by the presence of a radio-opaque marker on the pacemaker head, visible with x-ray, mentioning MLP:

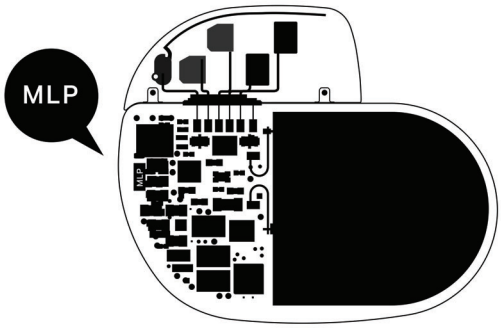
Device model	Device serial number with	Radio-opaque marker with
ALIZEA DR	GB	MLP
ALIZEA SR	GA	MLP
CELEA DR	GI	MLP
CELEA SR	GH	MLP

MLP specific X-ray marker

For the SR model:



For the DR model:



The following leads are MR Conditional when implanted with MR Conditional Devices:

Description	Lead name	Length
Active screw-in endocardial lead Atrial/Ventricular, Steroid	**VEGA R45**	45 cm
	VEGA R52	52 cm
	VEGA R58	58 cm

CAUTION: Any combination of the MR Conditional Devices with pacing leads other than the ones listed above may result in a hazard to the patient during MRI scanning.

NOTE: Please note that the non-MRI lead is identical to the MRI lead (Vega). When used with "*MRI conditional pacemakers*", the previously implanted "non-MRI" lead **does not need to be explanted**. It will become part of the new *MRI conditional* system in combination with an *MRI conditional* pacemaker.

. CONDITIONS FOR USE

When connected to an MR Conditional lead (see list in "Overview of the MR conditional products" section) the MR Conditional Devices enable a Full-Body MRI scan under the following conditions.

.1. FOR THE CARDIOLOGIST

Patients implanted with the MR Conditional pacing system can be safely scanned by an MRI system under the following conditions:

- The implanted system (pacemaker and leads) consists of a MR Conditional Device and MR Conditional lead(s) listed in "Overview of the MR conditional products" section.
- The MR Conditional Device is implanted in the left or right pectoral region.
- The MR Conditional Device and leads have been implanted for more than 6 weeks.
- The MR Conditional Device is programmed to enable the MRI Mode during MRI examination (MRI Mode can be programmed to Manual or to Automatic).
- Pacing capture threshold is 2.0 V or less at a pulse width of 0.35 ms or less.
- Lead is bipolar and its impedance is between Ω and Ω. The Programmer carries out this test automatically.
- Microport has defined a wide enough range for the MRI monitoring window to cover all the potential use cases. The default duration, automatically proposed at function activation, is 24 hours, which is adequate to cover an MRI test scheduled on the same day. Other durations may be programmed, upon explicit action by the physician. In such case, attention should be paid in selecting a duration sufficient to cover unexpected delays in the beginning of the MRI exam. In particular, the shorter durations of 2, 4 and 6 hours are recommended only when the MRI exam workflow is under strict control. In any case, it is suggested to advise the radiologist about the MRI window expiration time, so that the appropriate actions can be taken.
- Checklist item is approved on Programmer Screen to enable the MRI feature.

All conditions must be fulfilled. In particular, any combination of MR Conditional Devices with pacing leads other than the ones listed above may result in a hazard to the patient during MRI scanning.

CAUTION: Other implantation sites, such as abdominal implantation, have not been tested for MRI scanning safety. No data exist to support that MRI scanning in such cases is either safe or unsafe.

CAUTION: If the pulse generator is implanted in a patient who has other devices implanted in the chest area, MRI may be performed if the following conditions are fulfilled:

- All the other implanted devices are identified as MRI conditional by the respective manufacturers;
- The pulse generator and the leads are farther than cm from the other implanted devices.

CAUTION: When the MRI Mode is programmed to VOO or DOO, patients may exhibit a diaphragmatic or pectoral stimulation, as a result of a pacing output of 5.0 V. If MRI Mode is programmed to Auto, this effect may not appear before the pacemaker switches to asynchronous pacing, when in a strong magnetic field. Caution should be taken to test such a pacing mode prior to programming the MRI Mode. It is recommended to test the MRI Mode by manual programming at the time of the follow-up. Patients with diaphragmatic or pectoral stimulation are more likely to move during MRI scanning or may feel uncomfortable, which may compromise the outcome of the MRI scan.

.2. FOR THE RADIOLOGIST

The MRI mode (manual or automatic) has been programmed prior to the MRI exam.

Patients implanted with the MR Conditional system can undergo an MRI scan only under the following conditions:

— Magnetic resonance imaging of the hydrogen proton nucleus using a static magnetic field of 1.5T or 3T and, as a consequence, an excitation radiofrequency close to 64 MHz or 8 MHz.

— Horizontal cylindrical bore magnet, clinical MRI.

— For static magnetic field of T, whole Body Transmit Coil operating on Circularly Polarized (CP) RF excitation.

— Maximum spatial gradient of 20 T/m.

— Maximum gradient slew rate of 200T/m/s per axis.

— Patient does not have fever or a compromised thermoregulation at time of scan.

— Patient lies in the supine or prone position.

— There are no restriction for receive-only local coils; Transmit-only and transmit-receive local coils must not be used.

— Proper patient monitoring is provided during the MRI scan (use electrocardiography or pulse oxymetry or non-invasive blood pressure measurements).

— Whole body averaged specific absorption rate (SAR) as reported by the MRI equipment is .0 W/kg or less (.2 W/kg or less for head scanning). This can be easily achieved by selecting the Normal Mode in the MRI scanning parameters.

— The total duration of radio-frequency exposure (or the MRI total scanning time, excluding pauses between sequences) is less than 40 minutes.

NOTE: If the device or lead(s) are within or near the field-of-view of the MRI image, quality may be degraded by ferromagnetic artifacts caused by the MR Conditional system.

CAUTION:

An external defibrillator must be available during the MRI scan. If the patient's hemodynamic function is compromised during MRI scanning, discontinue the MRI scan, remove the patient from the MRI room and take the proper measures to restore the patient's hemodynamic function.

After external defibrillation, check for proper device function.

Visual monitoring of the patient and verbal communication are mandatory during the MRI scan.

. INDICATIONS

MR conditional system are listed above in "Overview of the MR Conditional products" section.

Please refer to the device user manuals for more details.

. CONTRAINDICATIONS

The patient shall be warned to inform the medical staff that he/she is implanted with an active implantable medical device before entering the MRI room and provide his/ her ID card if he/she received it.

The patient should be warned of the potential risks of pacemaker malfunction if he/she is exposed to external magnetic, electrical, or electromagnetic signals.

All conditions detailed in "Conditions for use" section must be fulfilled.

. ADVERSE EVENTS, RISKS AND SIDE-EFFECTS

The MR Conditional system has been designed and tested to minimize potential interactions with the MRI scanner. By programming the MRI Mode prior to MRI scanning, the following adverse events should be avoided but however may still occur in the MRI environment:

Mechanical Interactions:

The presence of ferromagnetic materials interacting with the static and gradient fields may induce force and vibration to the system.

Thermal Interactions:

Gradient and RF fields may induce warming of the device can and lead contact electrodes, which may damage the adjacent tissues, and eventually affect the lead pacing and sensing function.

Therapy Interactions:

The collected energy from gradient and RF fields may induce unintended cardiac stimulation and negatively affect the behavior of the device.

Residual potential interactions may still occur and the patient may feel physical sensations such as warm sensation, slight pulling or vibration at the implantation site which can lead to patient discomfort.

Artifacts may be observed if the implanted system is within the field of view (FOV) of the MRI scanner.

. MRI MODE

The MRI Mode is a pacing mode which is intended to be applied during MRI scanning.

CAUTION: MRI Mode is an asynchronous pacing at 5.0 V, ms pacing output, with a user-defined pacing rate or no pacing. Carefully consider the patient's condition before enabling MRI Mode.

.1. PROGRAMMABLE PARAMETERS

MRI Mode:

Programmable values: Auto, Manual, Off.

This parameter enables/disables the MRI Mode feature. Depending on specific needs, this parameter can be programmed to enable the MRI Mode automatically (triggered by the detection of a magnetic field) or manually.

MRI Mode set to Auto indicates that immediately after clicking on the [PROG] button, the MRI Mode is enabled, but not applied right away. The MR Conditional Device enters a monitoring phase. The programmer header bar displays "**MRI MODE: MONITORING**". As soon as a magnetic field is detected, the MR Conditional Device switches to "**MRI MODE: ACTIVE**" phase: MRI parameters are applied and pacing is either asynchronous (AOO, DOO or VOO) or suspended (OOO).

MRI Mode set to Manual indicates that immediately after clicking on the [PROG] button the device enters in MRI mode and all MRI parameters become active. The programmer header bar displays "**MRI MODE: ACTIVE**".

MRI Pacing Mode:

Programmable values: DOO, AOO, VOO, OOO.

This parameter indicates the pacing modality applied during the phase **"MRI MODE: ACTIVE".**

NOTE: Only asynchronous pacing or absence of pacing is permissible during an MRI scan. The electromagnetic interferences caused by the MRI equipment could induce noise in the MR Conditional Device. Allowing the pacemaker to sense atrial or ventricular contractions in such a noisy environment could lead to inappropriate pacing or inhibition of pacing.

MRI Pacing Rate:

Programmable values: 50-55-60-65-70-75-80-85-90-95-100-105-110- 5-120.

Default value = basic rate + 20 min^{-1}.

If an asynchronous pacing mode is selected, MRI Pacing Rate should be sufficiently high to avoid competitive pacing.

MRI Monitoring Period:

Programmable values: 2h, 4h, 6h, 12h, 24h, 48h, 3 days, 7 days, days.

When MRI Mode is set to Auto, this parameter defines the time window for the detection of a magnetic field which will trigger the asynchronous pacing mode (or absence of pacing when OOO is selected).

When MRI Mode is set to Manual, this parameter defines the time during which pacing will be asynchronous (AOO, VOO or DOO) or suspended (OOO).

NOTE:
Re-interrogation allows the interruption of the MRI Mode at any time before the end of the MRI Monitoring Period.

NOTES:

— DOO is available on MR Conditional Devices DR only.

— AOO is available on MR Conditional Devices DR and on MR Conditional Devices SR when set for the atrial cavity.

— When programmed to Automatic MRI Mode, after the magnetic field is no longer detected, MRI mode is maintained for a few minutes before resuming normal programming. In case the patient has to go back into the MRI equipment, the MRI mode will be applied as long as the MRI Mode Monitoring Period is not over and a magnetic field is detected.

— When programmed to MRI Mode, if the MRI Monitoring Period expires while the patient is still in the MRI environment, MRI mode is maintained until the magnetic field is no longer sensed. Then, the pacemaker will wait for a few minutes before resuming normal programming mode.

.2. ENABLING MRI MODE

CAUTION: The Programmer is MR Unsafe and should never be taken inside the MRI room.

Apply the following steps to enable the MRI Mode:

. In “Advanced Parameters” section of the “Parameters” tab, select "MRI parameters".

. Set MRI Mode to Manual or Auto.

. Adjust values for parameters:
  — MRI Monitoring Period
  — MRI Pacing Mode
  — MRI Pacing Rate

4. Program the MRI parameters by clicking on the [PROG] button.
5. A message is displayed with an MRI check list. Verify and click the check box to confirm all conditions are met.
6. The MRI Mode is enabled and MRI parameters will apply, either immediately (Manual) or when a magnetic field is detected (Auto). When interrogating the MR Conditional Device, the Programmer header bar will either display “MRI MODE: ACTIVE” (Manual) or “MRI MODE: MONITORING” (Auto).

NOTE: Depending on measurements carried out automatically, it is possible that MRI Mode cannot be enabled:

— when the device is too close to RRT (ERI),

— if bipolar impedance of one of the leads is out of the permissible range (or if a lead is unipolar).

In such a situation, an error message will be displayed on the Programmer user interface.

During phase **“MRI MODE: ACTIVE”**, the following parameters are set as follows:

— AV Delay = programmed Rest AV Delay (AV Delay extension =), the minimum AV Delay is 95 ms.

— Atrial / Ventricular amplitude = 5V or current programmed value if higher

— Atrial / Ventricular width = ms

— Atrial / Ventricular sensing polarity = Bipolar

— Atrial / Ventricular pacing polarity = Bipolar

Restrictions

During phase **"MRI MODE: ACTIVE"**, the Magnet Mode is replaced by the MRI Mode and all other features are deactivated or suspended due to asynchronous mode.

CAUTION: If the nominal mode is requested, for example by pushing the button on the telemetry head, the MRI mode is disabled.

NOTES:

— When the Programmer displays **"MRI MODE: ACTIVE"**, it is not possible to change device parameters. The only possible changes are to disable the MRI mode or to apply the nominal mode.

— It is possible to disable the MRI mode manually before the end of the MRI Monitoring period.

.3. DISABLING MRI MODE

When MRI Mode is programmed to Auto, asynchronous pacing or absence of pacing programmed as MRI parameters automatically reverts to the initial configuration approximately five minutes after the MR Conditional Device ceases to measure a magnetic field. It is preferable to keep the patient in a controlled medical environment until this mode switch has happened.

When MRI Mode is programmed to Manual, the MR Conditional Device automatically returns to the initial configuration at the end of the MRI Monitoring Period. However it is recommended to manually disable MRI Mode, in the programmer parameters screen by selecting value "OFF" for MRI mode, in order to avoid keeping the patient in asynchronous pacing or absence of pacing for an extended period of time.

At the end of the MRI Monitoring Period or after MRI Mode is manually disabled, the magnet mode becomes active again.

8. EXPLANATION OF SYMBOLS

The symbols on product labeling have the following meaning:

General symbols	Explanation of symbols
	Manufacturer
	MR Conditional
	Full Body
	MRI conditional
	This icon is used to call your attention to a particularly important point.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

MANUFACTURED IN ITALY

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MicroPort

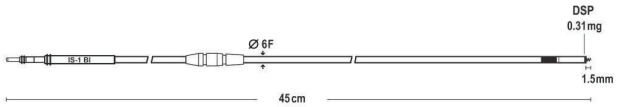
VeGa R45

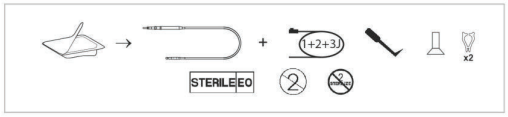
MR Conditional

BI

45 cm

7 F





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25°C
5°C
Store between 5-25°C
Excursion permitted to 0-50°C

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USA

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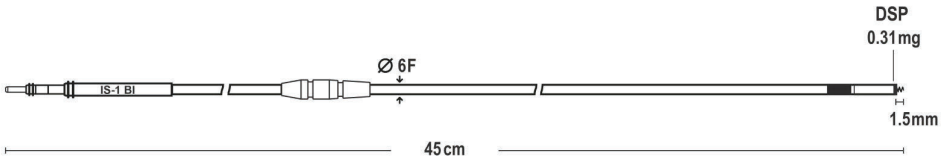
VeGa R45

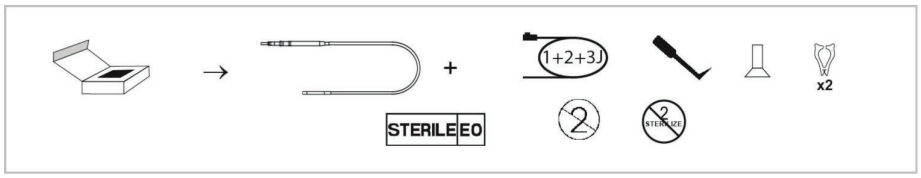
MR Conditional

BI

45cm **7 F**

USA





Store between 5-25°C
Excursion permitted to 0-50°C

Do not use if package is damaged

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Rx

REF TLD040U

SN XXXXXX
Serial number

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Use by

2021-07-22
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UA10446A-2

VeGa R45 MR Conditional
IS-1 BI 45cm 7 F
MicroPort

UA10446A-1

VeGa R45 MR Conditional
IS-1 BI 45cm 7 F
MicroPort

(01)08031527019789(11)210722(17)220822(21)XXXXXX

REF TLD040U

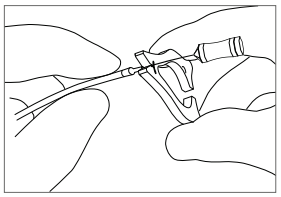
SN XXXXXX
Serial number

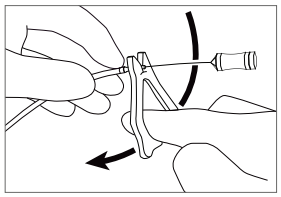
2022-08-22
(year-month-day)
Use by

2021-07-22
(year-month-day)
Date of manufacture

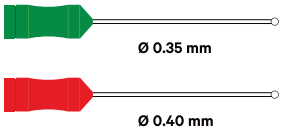
UA10446A

VEGA R45/R52/R58

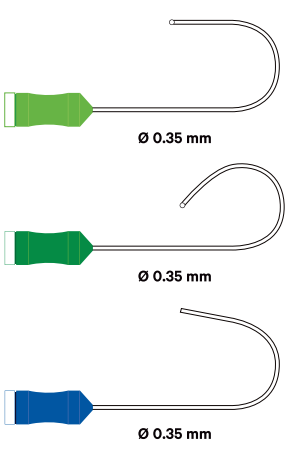




VEGA R45	8	14
VEGA R52	9	15
VEGA R58	10	16

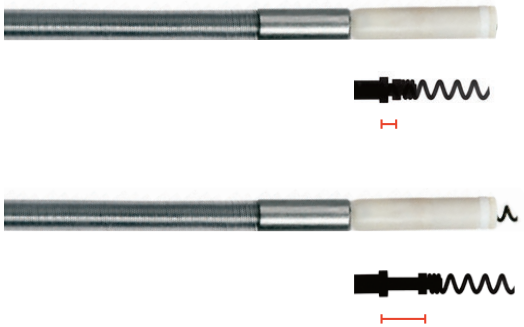


VEGA
R45/R52/R58



VEGA
R45/R52

MR conditional



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2020-05

UA10451A