LeMaitre®
VASCULAR

Disposable Angioscope

Disposable Angioscope
English — Instructions for Use

Disposable Angioscope

(Model Numbers ANG-080-D10K, A5000, eANG-080-D10K, eA5000)

Instructions For Use - English

Rx only | **STERILE EO**

Important

LeMaitre Vascular recommends a thorough review of the Instructions For Use before using the Angioscope.

Description

The angioscope can be introduced directly or in conjunction with a larger angiography catheter or introducer sheath. A working channel allows passage over a guidewire, use of instruments (with 2.3mm scope), and infusion or drainage of fluids. The instrument should be used only by physicians adequately trained in the proper techniques for performing these procedures.

Indications

The angioscope is a fiberoptic imaging catheter for visualization and assessment of the peripheral vasculature.

Contraindications

The use of the angioscope is contraindicated when, in the judgement of the physician, such a procedure would be contrary to the best interests of the patient.

Specifications

Model Number	Size	Irrigation Channel	Useable Length
ANG-080-D10K, eANG-080-D10K	2.3mm	1.0mm	80 cm
A5000, eA5000	1.7mm	0.8mm	100 cm

Warnings

1. Do not use if the product or sterile package is damaged.
2. The angioscope is supplied sterile and is for single use only.
3. Do not use the angioscope if the exterior wall is damaged.
4. Do not attempt to maneuver the angioscope in any vessel which is smaller than the diameter of the scope.
5. Do not attempt to advance or withdraw the angioscope against resistance until the cause of the resistance is determined. Movement of the scope against resistance may result in damage to the vessel and/or angioscope.
6. This device was designed and tested for single patient use only. Do not reuse, reprocess or resterilize this device. Reuse, reprocessing or resterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness or death. Risk of residual contamination and resterilization failure may lead to patient injury, infection, illness or death.

Precautions

1. For adequate illumination, the light cable must be properly connected to the light source and the light post of the angioscope. Water and/or other liquids present on either connector will result in decreased light transmission.
2. All electrical apparatus used with the angioscope must be in safe working order.
3. Handle with care; excessive manipulation of the angioscope or sharp blows to the instrument may result in damage to the optical system.
4. Scratching the lens or damaging the housing that surrounds the optical system may compromise the light or image quality.

Complications

As with all catheterization procedures, complications may occur. Complications may include, but are not limited to: pain, bleeding, hematoma, infection, clot formation or embolus, dislodging of atherosclerotic plaque, spasm, over hydration and vessel wall damage. Experience, along with awareness of the limitations of the instrument, has been the most significant factor in reducing the incidence of such complications.

Instructions for Use

1. Remove the instrument from its sterile package and check for any damage or malfunction. Examine the exterior surfaces of the scope for any damage, superficial cuts or abrasion. Do not use the unit if visible damage is present.
2. Check for patency of the irrigation lumen by injecting sterile saline or water through the irrigation channel.
3. Connect the appropriate end of any compatible light cable to the angioscope light post. Insert the other end into the light source. Check for adequate light intensity. A 300 watt Xenon light is recommended as a minimum light source. LeMaitre Vascular offers an assortment of light post adaptors if necessary for the proper fit.
4. A standard C-Mount adaptor is used to connect the eyepiece of the angioscope to the camera source cord. Follow the manufacturer's recommendations for operation of the camera source.
5. Check for clarity of image by visualizing a printed surface. If slight fogging of the image is present, clean the proximal and distal lens system with an alcohol swab. Recheck image quality. Do not use system if resolution and light intensity are not adequate for the scheduled procedure.
6. The angioscope may be introduced directly into the vessel or via an introducer sheath.
7. Under direct visualization the angioscope is cautiously advanced into the vessel. Care should be taken to avoid forcibly advancing the angioscope against any resistance.
8. Irrigant should be utilized to clear the field of view. The volume of irrigant used should be monitored closely to avoid over hydration of the patient.

9. Attempt to keep the angioscope in straight alignment with the vessel. This facilitates scope manipulation and reduces vessel wall friction.
10. Upon completion of the procedure, the angioscope should be slowly withdrawn, taking care to avoid excessive pulling, torquing or force.
11. The angioscope is discarded after use, according to standard hospital protocol.

How Supplied
Pyrogen testing has been performed on this device. This device is supplied non-pyrogenic. This device is supplied sterile and for single patient use.

Storage and Handling
The angioscope should be handled with care to prevent damage to the fiberoptic system. The angioscope may be stored in its original package in an area with good ventilation and protected from extremes of temperature and humidity. Handle with care. Product should be stored in a clean, cool, dry area away from chemical fumes.

Re-sterilization/Repackaging
This device is single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only. If for any reason this device must be returned to LeMaitre Vascular, place it in its original packaging and return it to the address listed on the box.

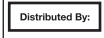
Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT,

INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Symbol Legend

					
English	Distributed By	Usable Length	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	Not made with natural rubber latex.	Consult instructions for use: https://eifu.lemaitre.com

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R2795-01 Rev.A 09/14