

DRAGONFLY™ OPTIS™

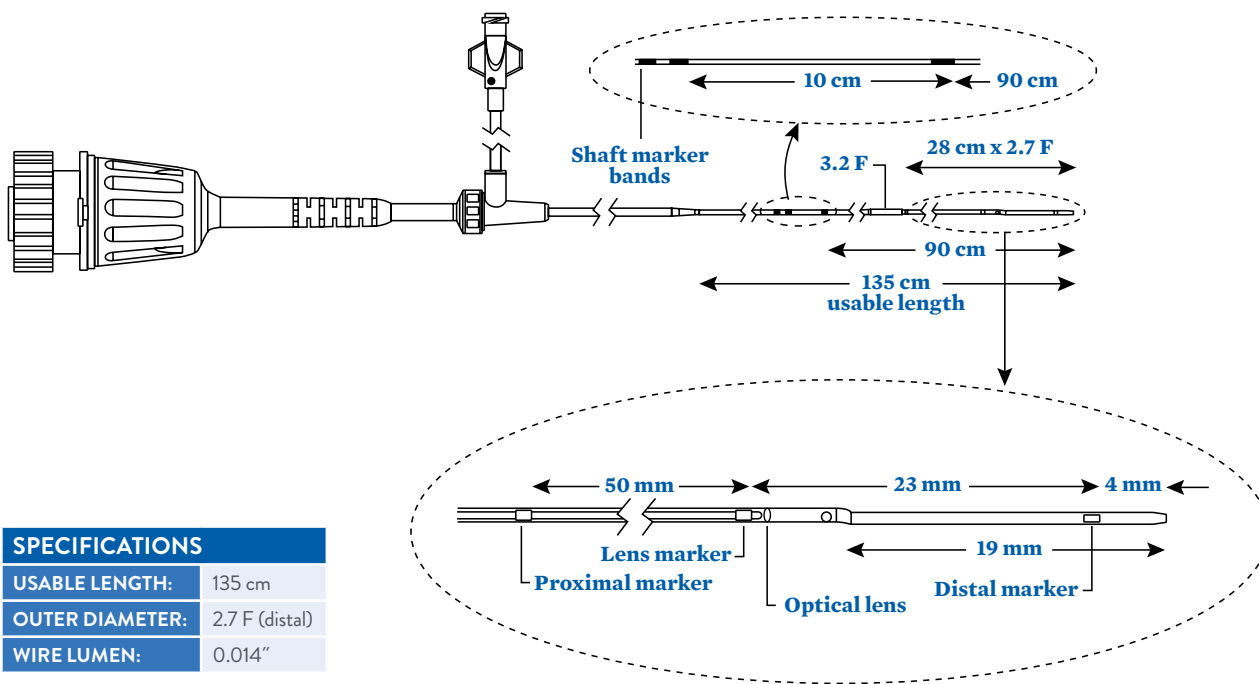
Imaging Catheter

HIGHER DEGREE OF ACCURACY

Product features

- OCT imaging catheter for OPTIS™ integrated system, ILUMIEN™ OPTIS™ and ILUMIEN™ PCI Optimization systems
- Proprietary sheath design provides continuous calibration throughout pullback
- Rapid exchange tip for easier Guide Wire loading
- Radiopaque markers at the distal tip, imaging lens and 50 mm proximal to the lens aid the physician in aligning the OCT pullback to region of interest
- Shaft markers at 90 cm and 100 cm notify the physician when the distal tip is exiting the guide catheter
- 2.7 F low-profile tip
- Hydrophilic coating
- Compatible with standard 0.014" Guide Wires
- Compatible with d.2 and e.2 Software or higher





SPECIFICATIONS	
USABLE LENGTH:	135 cm
OUTER DIAMETER:	2.7 F (distal)
WIRE LUMEN:	0.014"

ORDERING INFORMATION

DRAGONFLY™ OPTIS™	
REORDER NUMBER	DESCRIPTION
C408645	Dragonfly™ OPTIS™ Imaging Catheter
C408641	Dragonfly™ OPTIS™ Imaging Catheter and Sterile DOC Cover
C408646	Dragonfly™ OPTIS™ Imaging Catheter, Sterile DOC Cover and 1 Sterile 3 ml Syringe
200-700-00	Sterile DOC Cover
C408655	Sterile 3 ml Syringe

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. **Information contained herein for DISTRIBUTION in Europe, Middle East and Africa ONLY.** Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Tests performed by and data on file at Abbott. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott Vascular International BVBA

Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

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OPTIS™ MOBILE SYSTEM

Mobile Solution for OCT Angio Co-registration in Multiple Cath Labs

The OPTIS™ Mobile System is designed for use in multiple cath labs to combine OCT angio co-registration and FFR/RFR for more informed decision-making, greater efficiency and improved procedural effectiveness.

Angio co-registration advantage

- Provides confidence in OCT-guided PCI, synchronizing detailed OCT images and angiography
- May save time and reduce contrast/radiation exposure by obtaining OCT and angio simultaneously
- Completes cine and OCT acquisition in two to three seconds and requires only a single cine for co-registration

Gain procedural efficiency

- Allows multiple cath labs to be configured to one easily transportable cart
- Integration into the cath lab via easy pre-installed quick connections
- Includes a wireless tableside controller that provides full control of image acquisition and analysis at the bedside
- Supports centralized viewing of the OCT images on the boom monitor
- Delivers the same rapid OCT acquisition as the OPTIS Integrated System



ORDERING INFORMATION

OPTIS™ MOBILE SYSTEM	
ORDER NUMBER	DESCRIPTION
C408661	OPTIS™ Mobile System* OPTIS™ Mobile System console, Drive Motor and Optical Controller, OPTIS™ Tableside Controller, OPTIS™ Mobile Installation Kit (connectivity for a single cath lab allowing angio co-registration functionality)
C408662	OPTIS™ Mobile Upgrade Kit Includes all necessary components to upgrade an ILUMIEN OPTIS™ System to an OPTIS Mobile System, OPTIS™ Tableside Controller, OPTIS Mobile Installation Kit (connectivity for a single cath lab allowing angio co-registration functionality)
C408663	OPTIS™ Tableside Controller
C408666	OPTIS™ Mobile Installation Kit Connectivity for an additional cath lab allowing angio co-registration functionality for the OPTIS™ Mobile System

* Please contact your sales representative for site qualification and more detailed information.

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OPTIS™ INTEGRATED SYSTEM

For Truly Optimized PCI, It's Location, Location, Location

The OPTIS™ Integrated System provides precisely the information you need, exactly where you need it — for more informed decision making, greater efficiency and improved procedural effectiveness, especially in patients with complex lesions.

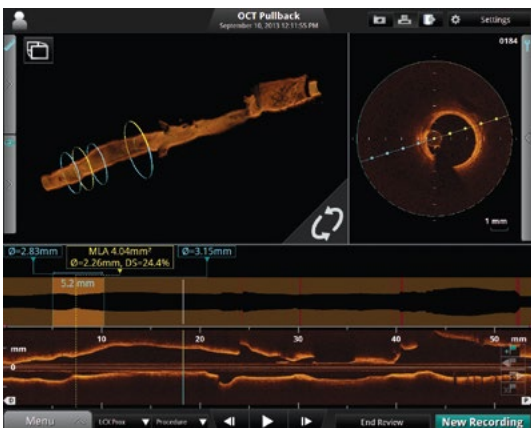
Right where you need it

This always-on, always-ready system is installed in the cath lab, eliminating setup time and giving you tableside control of OCT and FFR/RFR acquisition and review from the sterile field.

In addition to the workflow efficiencies offered by direct proximity, the on-demand availability of the OPTIS™ Integrated System optimizes PCI workflow without adding significant time.

Enhance procedures with:

- Wireless FFR/RFR
- Two to three second OCT pullback
- Rapid image processing
- Simultaneous angio and OCT image acquisition
- Real-time angio-OCT co-registration
- Seamless integration with cath lab IT systems



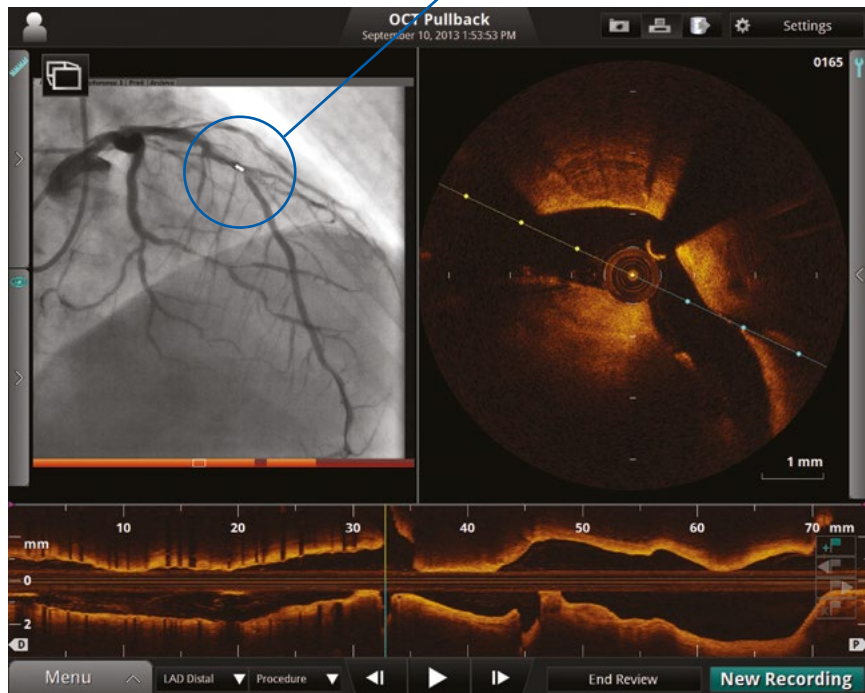
See where you want to see

Get stunning intra-lesion detail with real-time, OCT 3-D visualization. FFR/RFR combined with OCT informs PCI planning and decision making,¹ including:

- Lesion location and functional significance
- Lesion preparation¹
- Post-dilatation decisions¹
- Plaque morphology characterization^{2,3}
- Stent sizing and placement decisions⁴
- Optimal approaches to bifurcation stenting⁴
- Placement and apposition evaluations⁵
- Functional gain post-PCI

YOU ARE HERE

The OPTIS™ Integrated System synchronizes highly detailed OCT images with angiography to determine and **MARK LOCATIONS** within the coronary anatomy.



By integrating functional information with high-resolution anatomical detail and enhanced lesion visualization, the system facilitates more informed diagnostic and procedural decisions, leading to enhanced intervention planning and execution and, ultimately, improved patient outcomes.⁶

ORDERING INFORMATION

OPTIS™ INTEGRATED SYSTEM

ORDER NUMBER	DESCRIPTION
C408652	OPTIS™ Integrated System*

* Please contact your sales representative for site qualification and more detailed information.

1. B. De Bruyne, FAME 2 Trial Investigators. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. *New England Journal of Medicine* 2012, 367, 991-1001.
2. T. Kubo, Assessment of culprit lesion morphology in acute myocardial infarction. Ability of optical coherence tomography compared with intravascular ultrasound and coronary angiography. *Journal of the American College of Cardiology* 2007, 50, 933-939.
3. G.J. Tearney, International Working Group for Intravascular Optical Coherence Tomography (IWG-IVOCT), Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies: A report from the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation. *Journal of the American College of Cardiology* 2012, 59, 1058-1072.
4. T. Kubo, OCT compared with IVUS in a coronary lesion assessment: the OPUS-CLASS study. *JACC. Cardiovascular Imaging* 2013, 6, 1095-1104.
5. U. Allahwala, Clinical utility of optical coherence tomography (OCT) in the optimisation of Absorb bioresorbable vascular scaffold deployment during percutaneous coronary intervention, *EuroIntervention* 2014, 2015;10:1154-1159.
6. F. Prati, Angiography alone versus angiography plus optical coherence tomography to guide decision-making during percutaneous coronary intervention: The Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) study. *EuroIntervention* 2012, 8, 823-829.

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ILUMIEN™ OPTIS™

Offline Review Workstation

OCT OFFLINE REVIEW / ANALYSIS WORKSTATION

The OCT Offline Review Workstation (ORW) is a proprietary hardware/software station designed specifically for analyzing the data imported from the Abbott intravascular OCT imaging systems.

The Workstation is both powerful and easy to use, employing familiar point-and-click and menu selection techniques, allowing quick review and analysis of OCT

images. It provides the flexibility to complete post procedure measurements whenever and wherever the clinician desires.

This powerful analysis tool provides the information and insights you need to perform multiple data point analyses quickly and accurately.



Product highlights:

- Complete portable analysis solution to provide flexible offline image review workflow
- Multiple view options to easily zoom in and customize areas of interest
- Broad menu of automated measurements for quick and accurate assessment
- Variable axis lateral view (L Mode) for visualization of the full image from different perspectives. This user configured option gives the analyst a multi-dimensional perspective for more informed decisions.
- Multifunction image management toolbar allows quick refinements and selections. Many of the configurations are accessible for individual user configurations.
- Multiple data management options for flexibility and customization. Output image files to external storage over your network or with a variety of external storage media. Manage files as DICOM, MPEG, AVI, TIFF, or JPEG for a range of compression options and transfer methods.

ORDERING INFORMATION

ILUMIEN™ OPTIS™

REORDER NUMBER	DESCRIPTION
C408651	Computer, monitor, keyboard, mouse and software

Note: The Offline Review Workstation is not for use in the diagnosis of disease or other conditions, or for use in the cure, mitigation, treatment, or prevention of disease. The workstation computer and the monitor are classified as Non-Medical Devices.

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APTIVUE™

Software for the OPTIS™ System

STATE-OF-THE-ART CORONARY PHYSIOLOGY AND OCT IMAGING ON ONE PLATFORM

Automated stent expansion calculations

- Easily determine areas of stent under expansion along the entire stented region to ensure maximum lumen gain

Resting Index, Resting Full-Cycle Ratio (RFR)¹

- Identifies ischemia-causing lesions without hyperemia
- Allows pullbacks to assess serial lesions and diffuse disease

AptiVue™ software also features:

- Angio co-registration
- Apposition indication
- Automatic measurements for stent planning
- Bifurcation tools
- Fractional Flow Reserve (FFR)



ORDERING INFORMATION

APTIVUE™ SOFTWARE FOR OPTIS™

REORDER NUMBER	DESCRIPTION
1014663	AptiVue™ Software Upgrade Kit (E.5.1)
1014664	AptiVue™ Software Upgrade Kit (E.5.1) – Offline Review Workstation

I. J. Svanerud, VALIDATE RFR, EuroIntervention, 2018.

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