”萊特萊柏”光學同調斷層掃描影像系統

”LightLab” Optical Coherent Tomography Imaging System

衛署醫器輸字第 022593 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

型號：C7 XR、13751-02

產品敘述：

本案包含

主機：C7 XR OCT 影像系統

配件：C7 飛龍影像導管(C7 Dragonfly Imaging Catheter), Model: 13751-02

光學同調斷層掃描（OCT）是一種利用光纖成像的技術。C7 XR 影像系統使用光學影像導管能發出近紅外光來產生高清晰度的即時圖像。

注意：操作 C7 XR OCT 影像系統的醫務人員必須了解系統的局限性。只有經過培訓的人員可以判斷如何適當使用本系統。在第一次操作影像系統之前，請務必閱讀第 13 章“安全訊息”。

產品用途：

LightLab C7 XR 光學同調影像系統及 C7 飛龍影像導管用於提供冠狀動脈影像，並適用於需要腔內介入性治療的病人。C7 飛龍影像導管適用的血管直徑介於 2.0 到 3.5 mm。C7 飛龍影像導管不適用於左主冠狀動脈或目標血管曾做過繞道手術。

C7 XR 的組件

LightLab C7 XR 光學同調影像系統包括以下組件，可整合成一個移動台車：

- 成像引擎。
- 兩台監視器。
- 一個驅動馬達和光學控制器（DOC）。
- 一個獨立變壓器。
- 一台電腦，鍵盤和滑鼠。

注意：電腦是 C7 XR 光學同調影像系統的其中一個組成部件，客戶不得以任何方式修改其硬體跟軟體。作出這樣的修改可能會干擾正確的操作而且將喪失保固。

注意：C7 XR 光學同調影像系統需經接受過訓練的醫務人員才能操作。 LightLab 公司及其雇員，不能在解釋或診斷圖像時給予指示。

禁忌症

禁止使用飛龍影像導管在任何可能威脅病人的安全的地方。

禁忌症包括：
菌血症或敗血症
主要凝血系統異常
不可進行冠狀動脈搭橋手術的患者
不可進行 PTCA 的患者
血流動力學不穩定或嚴重休克
患者診斷為冠狀動脈痙攣
共有閉塞
大血栓
急性腎功能衰竭

警告及注意事項：
操作人員必須接受 LIGHTLAB 訓練後才能使用。
請詳閱讀所有的注意事項後才能操作，並且遵守說明中所有警告和注意事項否則將可能產生併發症。
◆在常溫下儲存在乾燥處避免太陽直射。
◆本裝置經環氧乙烷滅菌，供一次性使用，無熱原。如果包裝被打開或有破損請勿使用。不可重複使用或重覆消毒。
◆使用程序中視需要適當的使用的抗凝和擴張血管的治療。
◆在螢光顯示下觀察飛龍導管的前進及移動。導管前進或撤回時均須緩慢進行。不遵守導管在螢光顯示下的運行可能會導致血管受損或機器的損壞。導管定位之後就不要再移動導線以確保正確的定位。
◆若導管前進或後退的過程中受到阻力，應停止操作並且在螢光幕下在審慎的評估。
◆若產生阻力的原因無法被偵測到或是減輕，小心的將導管從患者的體內取出。
◆使用最低的沖洗率及所需的體積來呈像。
◆本產品使用後會產生潛在的生物危害，請依一般醫療規範處理。
◆造影劑的使用及預防措施請參閱該說明及一般警告預防措施。
◆在使用過程中隨時查看導管及導線是否同時進行，在退出導管之前不要退出或前進導絲。
◆導管不可以強行進入小於導管主體之管腔或強行通過緊縮的鈣化病變處。
◆導管不可以通過解剖上異常曲折處。
◆當前進或收回導管經過支架置放的血管，導管及導絲交界處可能會勾到支架，導致導管/導絲卡住、導管尖端分離，及/或支架易位。
◆以下患者群的安全性及有效性已經確立：成人在病變處參考血管直徑介於 2.0-3.5 mm 之間，接受非急性經皮冠狀動脈介入治療，其中不包括左主冠狀動脈或目標血管曾做過繞道手術。
◆所有操作者必須經過培訓才能使用 C7 XR 光學同調影像系統及 C7 飛龍影像導管。
◆只有 100%的造影劑可獲准使用於人體。
◆導管應儲存於常溫乾燥處，避免太陽直射。

◆切勿嘗試將導管從 DOC 上連接或拆離，除非綠色加載 LED 燈發亮且不閃爍。
◆任何時候都不可以用外力扭曲、捏或壓碎導管。
◆導管是一次性使用，不可重複滅菌使用。
◆導管是由環氧乙烷滅菌，旨在為一次性使用，無熱源。如果包裝被打開或破損，則不可以使用。
◆使用後導管會有潛在的生物危害，處理或棄置應按照一般醫療儀器適用法規。
◆導管沒有維修的部件，請不要試圖修理或改變任何部分。

併發症

所涉及的風險包括血管成像與所相關的導尿程序。以下的併發症(依字母排序)是為結果，可能會出現在血管內成像的過程中，並且可能需要額外的治療，包括外科手術治療。

冠狀動脈痙攣
不穩定型心絞痛
造影劑過敏
動脈損傷或穿孔
血栓形成，突然關閉，或完全阻塞
不正常的心臟心律失常
栓塞
急性心肌梗塞
死亡

系統規格--參數規格：

參數	**規格**
輸入功率	
線路電壓	100V/120V/220V/240V ± 10%; 50/60 ± 1 赫茲
電源功率	消耗：< 400 VA 待機：< 30 VA
運輸與儲存條件（允許範圍）	
環境溫度	攝氏-25 至+50 度
相對濕度	10% - 95%
大氣壓力	500 至 1060 mBar
工作條件	
環境溫度	攝氏+10 至+32 度
相對濕度	30%至 80%，無冷凝
大氣壓力	700 至 1060 mBar

機械規格

重量	95 公斤（209 鎊）含所有配件之最大值
外形尺寸	145cm 高 x 61cm 寬 x 71cm 深 ± 5 mm

成像規格

參數	規格
光學參數 - 在系統測量孔徑（DOC 光學孔）	
掃描雷射光源光功率	22.6 mW 最大值@ 1305 ± 55 nm （Class 1M 雷射輸出符合 IEC 60825-1）
可見光光功率	1.45 mW 最大值@ 670 納米（標稱） （Class 2M 雷射輸出符合 IEC 60825-1）
拉回參數	
拉回範圍（深度）	50 毫米
拉回速度設定	10，15，20，25 毫米/秒
一般掃描參數	
空氣 A 掃描範圍	7.0 mm
介質 A 掃描範圍	4.83 mm
直徑測量精確度	7% ±0.1 mm
面積測量精確度	10% ±0.1 mm^2
軸向解析度	≤ 20 μm in tissue
橫向解析度	25-60 μm
光學靈敏度	90 db minimum
A 掃描每秒鐘	50,400 Hz
幀速率	100 frames/second(Hz)

C7 XR 光學同調影像系統及 C7 飛龍影像導管規格摘要：

影像規格	
線速率(A-掃描速率)	50,400 lines/second
畫面更新率	100 frames/second
每畫面線數	504 lines/frame
掃描半徑 空氣中 對比中	 7.00 mm 4.83 mm
縱向解析度	額定 16 um, 最大 20 um
掃描雷射功率及 頻寬	12 至 22.6 mW > 90 nm 為中心 於1310 nm
拉回參數	

拉回啟動模式	壓力啟動；軟體啟動
拉回速率	20 mm/second
拉回長度	50 mm
拉回時間	2.5 seconds
血液擴清參數	
注射器材	自動注射幫浦
注射介質	顯影劑
注射速度	4 ml/second
注射容積	14 ml
注射時間	3.5 seconds
導管規格	
導管種類	滅菌，一次性使用冠狀動脈成像導管
導管傳送方式	快速交換(透過 Minirail tip)
遠端交叉形狀	2.7 Fr 外徑(0.036”)
可用長度	135 cm
導引導管相容性	與無側孔之 6 Fr, 7 Fr 及 8 Fr 導引線相容
導引線相容性	與所有一般 0.014”導引線相容
量測規格	
量測精確度 管徑直徑	± 7% ± 0.10 mm 的測量
量測精確度 管徑區域	± 10% ± 0.10 mm^2 的測量
配件	
提供配件	3 ml syringe（滅菌一次使用） DOC bag（滅菌一次使用）
選配	壓力傳導器(滅菌一次使用) 離線複查工作站

C7 Dragonfly Imaging Catheter（型號：13751-02）
規格：
長度 135 cm
遠端外徑：2.7 Fr (0.036 inch)
線內腔：0.014 Inch
塗層：親水層

製造廠名稱：LightLab Imaging, Inc.
製造廠地址： One Technology Park Drive Westford, MA 01886, USA
藥商名稱：台灣聖猷達醫療用品有限公司
藥商地址：臺北市內湖區瑞光路 407 號 5 樓

System Overview 1

This chapter provides a description of the C7 XR OCT Imaging System and its components. Included in this chapter are:

- System features.
- System components, including the System in Cart, the System Display, and the DOC.
- Indications for use.

LightLab C7 XR OCT Imaging System Features

Optical Coherence Tomography (OCT) is an imaging modality that utilizes fiber-optic technology. The C7 XR OCT Imaging System uses optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. The wavelengths and bandwidths of infrared light are far higher than medical ultrasound signals, resulting in greatly increased image resolution.

CAUTION: Medical personnel who use the C7 XR OCT Imaging System must be aware of the system's limitations. Only trained operators can determine if the C7 XR use is appropriate. Be sure to read Chapter 13 "Safety Information", before operating the imaging system for the first time.

In addition to controlling basic imaging functions, the C7 XR OCT Imaging System lets you:

- Acquire, save, and subsequently retrieve images for review.
- Review previously acquired images in L-Mode (lateral view).
- Overlay color maps to optimize contrast for viewing images.
- Enlarge a defined area of interest (zoom).
- Make measurements and calculations.
- Add text annotations.

- Play back and edit images with a full range of playback and editing capabilities.
- Export still images and movies in raw OCT format or in standard AVI, TIFF, JPEG, BMP, or DICOM formats.
- Import LightLab OCT format images and review and edit them with full OCT review and edit capability.
- Perform basic file management functions.

C7 XR Components

The LightLab C7 XR OCT Imaging System includes the following components[1], integrated into a mobile cart:

- An imaging engine.
- Two monitors.
- A Drive-motor and Optical Controller (DOC).
- An isolation transformer.
- A computer, a keyboard, and a mouse.

CAUTION: The computer is an integral part of the C7 XR OCT Imaging System and its hardware and software must not be modified in any way by the customer. Making such modifications may interfere with correct operation and will void system warranties.

See Chapter 14 “System Specifications” for important classification information for components.

1. Brands and models of components may vary from those shown in this manual.

Prescriptive Information 3

This chapter provides prescriptive information related to the use of the LightLab® C7 XR™ Imaging System with the C7 Dragonfly™ Imaging Catheter. Included in this chapter are:

- Indications for use, contraindications, and complications.
- Warnings and precautions related to the use of the catheter.

Prior to use please see the complete "Instructions for Use" supplied with the C7 Dragonfly Imaging Catheter for more information.

CAUTION: The C7 XR Imaging System with the C7 Dragonfly Imaging Catheter is intended for use by appropriate medical personnel who have received C7 XR training. LightLab Imaging Inc., and its employees, cannot give instructions in the interpretation or diagnosis of images and makes no attempt to do so.

Indications for Use

The LightLab® C7 XR™ Imaging System with the C7 Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

Contraindications

Use of the LightLab® C7 XR™ Imaging System with the C7 Dragonfly™ Imaging Catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety.

Contraindications (listed alphabetically) include:

- Bacteremia or sepsis

- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Total occlusion

Warnings

- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Observe all advancement and movement of the Dragonfly Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during advancement or withdrawal of the Dragonfly Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- The catheter should never be forced into lumens that are narrower than the catheter body or forced through a tight or heavily calcified lesion.
- The catheter should not be advanced through abnormally tortuous anatomy.
- When advancing or retracting a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- Refer to the contrast media's instructions-for-use for general warnings and precautions relating to use of the contrast media.

Precautions

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.

- All operators must be trained prior to using the C7 XR Imaging System and the C7 Dragonfly Imaging Catheter.
- Only 100% contrast media is approved for human use.
- Store the catheter at ambient temperature in a dry location out of direct sunlight.
- Never attempt to attach or detach the catheter to the DOC unless the green Load LED is illuminated and not blinking.
- Do not kink, sharply bend, pinch, or crush the catheter at any time.
- The catheter is for single use only. Do not reuse, re-sterilize, or reprocess.
- The catheter is sterilized by ethylene oxide and is intended for one time use only. Non-pyrogenic. Do not use if the package is opened or damaged.
- After use, the catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.

Complications

The risks involved in vascular imaging include those associated with all catheterization procedures. The following complications (listed alphabetically) may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention.

- Acute myocardial infarction or unstable angina
- Allergic reaction to the contrast media
- Arterial dissection, injury, or perforation
- Cardiac arrhythmias
- Coronary artery spasm
- Death
- Embolism
- Thrombus formation

System - Electrical and Physical

Table 14-2: System Electrical and Physical Specifications

Parameter	Specification
Power Input	
Line voltage	100/120/220/240 VAC ±10%, user selectable
	50/60 Hz ±1 Hz
Power consumption	Active: < 400 VA
	Standby: < 30 VA
Transport and Storage Conditions (Permissible ranges)	
Ambient temp	-25 to +50 degrees C
Relative humidity	10% - 95%, including condensing
Atmospheric pressure	500 to 1060 mBar
Operating Conditions	
Ambient temperature	+10 to +32 degrees C
Relative humidity	30% to 80%, non-condensing
Atmospheric pressure	700 to 1060 mBar
Mechanical Specifications	
Weight	95 kg (209 lbs) max with all accessories
Overall Dimensions	145 cm H x 61 cm W x 71 cm D ±5 mm

Imaging

Table 14-3: Imaging Specifications

Parameter	Specification
Optical Parameters - Measured at System Aperture (DOC Optical Port)	
Scanning Laser Source Optical Power	22.6 mW maximum @ 1305 nm ±55 nm (Class 1M Laser Output per IEC 60825-1)
Visible Laser Optical Power	1.45 mW maximum @ 670 nm (nominal) (Class 2M Laser Output per IEC 60825-1)
Pullback Parameters	
Pullback Range	50 mm
Pullback Speed Settings	10, 15, 20, 25 mm/sec

Table 14-3: Imaging Specifications *(continued)*

Parameter	Specification
General Scan Parameters	
A-Scan Range in Air	7. 0 mm
A-Scan Range in Contrast	4.83 mm
Diameter Measurement Accuracy	7% ±0.1 mm
Area Measurement Accuracy	10% ±0.1 mm^2
Axial Resolution	≤ 20 µm in tissue
Lateral Resolution	25 - 60 µm
Optical Sensitivity	90 db minimum
A-Scans per second	50,400 Hz
Frame Rate	100 frames/second (Hz)

Electromagnetic Emissions

The LightLab C7 XR OCT Imaging System is intended for use in the electromagnetic environment specified in Table 14-4, Table 14-5, Table 14-6, and Table 14-7 in this section. The customer or user should assure that the system is only used in such an environment.

Table 14-4: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The C7 XR OCT Imaging System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The C7 XR OCT Imaging System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic proposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

15.0 Sterility and Packaging

The Dragonfly Catheter is a sterile, single use device. It is sterilized using ethylene oxide. Details regarding the sterilization cycle are provided in **Section 5** of this application.

The Dragonfly Catheter is packaged in a circular hoop to provide the device in a convenient sized package. (The catheter is over 130 cm in length.) The Dragonfly Catheter is to be removed from the hoop prior to preparation and purging before use.

16.0 Key System Performance Specifications

This section summarizes the key system specifications of the C7 System and Dragonfly Catheter. The specifications are summarized in Table 7. Please note that for imaging specifications, scan radius is provided in contrast solution since vessel lumen is filled with contrast solution during OCT imaging. Axial Resolution is specified in saline solution since this parameter is most relevant to imaging of vessel wall tissue, which is composed mainly of saline.

Table 7: Summary of Key Performance Specifications for the C7 System and Dragonfly Catheter

Imaging Specifications:	
Line Rate (A-scan rate)	50,400 lines/second
Frame Rate	100 frames/second
Lines Per Frame	504 lines/frame
Scan Radius In air In contrast	 7.00 mm 4.83 mm
Axial Resolution	16µm nominal, 20µm maximum
Scanning Laser Power and Bandwidth	12 to 22.6 mW and > 90 nm centered at 1310 nm
Pullback Specifications:	
Pullback Trigger Modes	Pressure Trigger, Software Trigger
Pullback Rate	20 mm/second
Pullback Length	50 mm
Pullback Time	2.5 seconds
Blood Clearance Specifications:	
Injection Device	Automated Injection Pump
Injection Media	Contrast Solution
Injection Rate	4 ml/second
Injection Volume	14 ml
Injection Time	3.5 seconds
Catheter Specifications:	

Catheter Type	Sterile, single-use coronary imaging catheter
Catheter Delivery Method	Rapid exchange (via minirail tip)
Distal Crossing Profile	2.7 Fr outside diameter (0.036")
Usable Length	135 cm
Guide Catheter Compatibility	Compatible with 6 Fr, 7 Fr and 8 Fr guide catheters without side holes
Guide Wire Compatibility	Compatible with all common 0.014" guide wires
Measurement Specifications:	
Measurement Accuracy, Lumen Diameter	± 7% of measurement ± 0.10 mm
Measurement Accuracy, Lumen Area	± 10% of measurement ± 0.10 mm^2
Accessories:	
Supplied Accessories	3 ml syringe (sterile, single use), DOC bag (sterile, single use)
Optional Accessories	Pressure Transducer (sterile, single use), Off-line Review Workstation

17.0 Installation and Service

The C7 System installation is performed by LightLab employees or trained designees following the C7XR Quick Installation Guide 14091. Once the system is uncrated, assembly is performed using only two supplied hex wrenches and takes less than an hour. At installation the Imaging Engine and monitors are added to the pre-assembled cart base, and cable interconnections are made.

Once assembled, the system is tested according to the C7 XR Field Test 14284. Optical characteristics of the system are verified using a calibrated reflectance test fixture. With this fixture the measurement resolution and detection range (SNR) of the system are verified. Mechanical integrity of the system is then verified by the loading a Dragonfly Catheter, and performing a test imaging pullback sequence. Data collected while performing the test are captured on a standard form template which is returned to LightLab and filed with the system Device Master Record.

LightLab® Dragonfly™ Imaging Catheter

Instructions for Use

PRECAUTIONS and WARNINGS

ALL OPERATORS MUST BE TRAINED BY A LIGHTLAB REPRESENTATIVE PRIOR TO USE.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS; OTHERWISE, COMPLICATIONS MAY OCCUR.

Store at ambient temperature in a dry location out of direct sunlight.

This device is sterilized by ethylene oxide and is intended for one time use only. Non-pyrogenic. Do not use if the package is opened or damaged. Do not reuse or re-sterilize.

Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.

Observe all advancement and movement of the Dragonfly™ Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage. To assure proper placement do not move the guide wire after the Dragonfly™ Imaging Catheter is in place.

If resistance is encountered during advancement or withdrawal of the Dragonfly™ Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter from the patient.

Use the minimum flush rate and volume required to image the desired anatomy.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Refer to contrast media instructions-for-use for general warnings and precautions relating to contrast media.

INDICATIONS FOR USE

The Dragonfly™ Imaging Catheter and LightLab® C7-XR™ Imaging System are intended:

1. For qualitative and quantitative evaluation of vascular morphology in the coronary arteries

2. As an adjunct to conventional angiographic procedure to provide an image of vessel lumen and wall structures

3. For the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedure.

CONTRAINDICATIONS

Use of the Dragonfly™ Imaging Catheter *is contraindicated where introduction of any catheter would constitute a threat to patient safety.*

Contraindications include:

Bacteremia or sepsis

Major coagulation system abnormalities

Patients disqualified for CABG surgery

Patients disqualified for PTCA

Severe hemodynamic instability or shock

Patients diagnosed with coronary artery spasm

Total occlusion

Large thrombus

Acute renal failure

COMPLICATIONS

The following complications may occur as a consequence of intravascular imaging:

Coronary artery spasm

Unstable angina

Allergic reaction to the contrast media

Arterial dissection, injury or perforation

Thrombus formation, abrupt closure, or total occlusion

Abnormal heart arrhythmias

Embolism

Acute myocardial infarction

Death

DESCRIPTION

The Dragonfly™ Imaging Catheter consists of two main assemblies: the catheter body and the internal rotating fiber optic imaging core. The distal catheter is 2.7 Fr. in outside diameter (0.036") and has a usable length of 135 cm. It is a rapid exchange ('RX') design with a 'minirail' tip, having 19mm of guide wire engagement length. The catheter has a hydrophilic coating. The Dragonfly™ Imaging Catheter is designed for compatibility with 0.014" steerable guide wires used during coronary interventional procedures.

Just proximal to the minirail tip is the imaging area which is 5 cm in length. During image acquisition the fiber optic core of the Dragonfly™ Imaging Catheter rotates and is automatically retracted within the catheter to obtain a 360° image of the artery and obtain a continuous pullback image of an arterial segment.

There are two radiopaque markers (RO marker) separated by 20 mm; outside edge to outside edge (19mm center to center). The distal marker (minirail tip marker) is placed 5 mm from the tip of the catheter to maintain tip flexibility, and the proximal marker (lens marker) is placed 3mm distal to the initial imaging lens position prior to pullback. Within the catheter, the internal rotation of the fiber optic imaging core is driven by a stainless torque wire which can also be seen under fluoroscopy.

A luer fitting on the side-arm at the proximal end of the catheter facilitates purging the central catheter lumen with 100% contrast media prior to use. A 3cc syringe is required to perform catheter purge. The catheter purge must be performed prior to imaging. The 3 cc syringe should be left attached to the sidearm to allow repeated purging throughout the imaging procedure and maintain a static pressure to prevent backflow.

The Dragonfly™ Imaging Catheter connects to the C7-XR™ Imaging System through the Drive-motor and Optical Connector (DOC 2.0™). All fiber optic rotation and translational pullback is driven by the DOC 2.0™ and occurs inside the catheter.

Refer also to Figure 1.

MATERIALS AND EQUIPMENT

(Not packaged with the Dragonfly™ Imaging Catheter *disposables)*

LightLab C7-XR™ Imaging System and DOC 2.0™

Sterile DOC 2.0™ cover

3cc purge syringe

Contrast media indicated for coronary use, for purging and flush

0.014" guide wire (with torque device if desired)

Guide catheter (6 French, 0.070" ID or larger, with no side holes)

Sheath introducer (to match guide catheter)

Hemostatic Y-Adapter/Connector

Heparinized, physiologic saline solution, for hydrophilic catheter preparation

Automated power injector pump (capable of injecting 3.0-4.0cc/sec for a total of 14cc in 3.5 seconds) (optional)

PREPARATION FOR USE

1. Refer to the C7-XR™ Imaging System Reference Manual for instrument preparation.
2. Using sterile technique, remove the Dragonfly™ Imaging Catheter from its sterile package. Examine for visible damage or defects.
3. Set automated injector pump settings to:
    - 4cc/sec or less flush rate.
    - 14cc total flush volume, for 3.5 seconds
    - Pressure limit 250 psi, or the nearest available setting.

Dragonfly™ Imaging Catheter Preparation

1. Carefully remove the catheter from the hoop.
2. Moisten the distal segment of catheter from tip to approximately 100cm proximally, using heparinized saline only.

Note: Moistening ensures optimal performance of hydrophilic coating. Use heparinized saline only; alcohol will damage the coating.

3. Flush the Dragonfly™ Imaging Catheter's lumen with 100% contrast media to remove all air from catheter. Use a 3 cc syringe and flush until 3-5 drops exit from the catheter distal tip. Do not remove this syringe from the catheter flush port.

Connecting the Dragonfly™ Imaging Catheter to the DOC2.0™

This connection procedure requires 2 operators; a sterile operator and a non-sterile operator. All steps requiring contact with the Dragonfly™ Imaging Catheter or the outside of the sterile DOC 2.0™ cover must be performed by the sterile operator. All steps performed within the sterile DOC 2.0™ cover or in direct contact with the C7-XR™ Imaging System must be performed by the non-sterile operator.

(Non-sterile Operator) Place the DOC 2.0™ inside a sterile DOC 2.0™ cover and extend the cover over the DOC 2.0™ cable to its full length

(Sterile Operator)

1. Partially withdraw the imaging catheter hub from the hoop and twist off the protective cap.
2. Ensure DOC 2.0™ green light is illuminated and not blinking, indicating it is ready to connect. Open the black protective cap on the DOC 2.0™ to access the connection port for the internal optical connector.
3. Insert the white catheter hub through the opening in the sterile DOC 2.0™ cover.

CAUTION: Protect the exposed connector from fluids at all times. Fluid contact can disable the DOC2.0 and require service.

4. Holding the finger grips on the white catheter hub, align the four corners of the hub with the DOC 2.0™ open black connection port.
5. Insert the hub into the port. Twist the hub to engage, ¼ turn clockwise until secure.
6. You will hear the DOC 2.0™ automatically make the internal optical fiber connection. The DOC 2.0™ green light will flash during this process.
7. When the green light stops blinking and remains steady, the C7-XR™ System will start rotation of the imaging core and set the Z offset automatically. (See the C7-XR™ Reference manual for details.)
8. Carefully hold the catheter lens (at the point of the visible red light) between thumb and finger so that the sterile gloves surface image is visible on the OCT monitor.

(*Non-sterile Operator)*

9. Adjust the Z offset so the catheter sheath outer ring is aligned with the fiducial marks. If any distortion or indication of optical breakage appears during the Z offset process, replace the catheter before proceeding.
10. Have the non-sterile operator click "Stop Scanning".

Refer also to Figure 2.

Connecting Injector Pump to Guide Catheter

(Sterile Operator)

Connect the automated injector pump output to one port of the guide catheter manifold, and purge all air from the tubing and manifold.

Refer also to Figure 3.

INSTRUCTIONS FOR USE

CAUTIONS

Ensure that no air is introduced into the system during the imaging catheter insertion.

Monitor the OCT image for indications of catheter optical failure. If optical failure is suspected, remove the catheter and replace with a new one.

Dragonfly™ Imaging Catheter Insertion and Placement

1. Ensure the guide catheter is oriented to preferentially direct contrast flow to the target lesion, and verify angiographically that adequate flow of contrast is delivered to the lesion.
2. Back-load the Dragonfly™ Imaging Catheter's rapid-exchange lumen onto the indwelling .014" guide wire.

The imaging catheter has two radiopaque marker bands (RO marker). The distal RO marker (minirail rip marker) is located 5mm from the catheter tip. The proximal RO marker (lens marker) is 3mm distal to the imaging fiber lens. The distance between the two markers is 20 mm.

3. Under fluoroscopic guidance, advance the catheter until the **proximal marker** (lens marker) is positioned **5mm distal** to the desired position for pullback initiation.

In Vivo Imaging

1. Start live scanning with the C7-XR™ Imaging System.
2. Purge the Dragonfly™ Imaging Catheter by injecting ~0.1cc contrast using the 3 cc syringe to ensure no image-obscuring blood has diffused into the catheter lumen.

NOTE: Application of negative pressure to draw blood into the catheter is **not** recommended. Blood will obscure the image and can be difficult to completely purge.

3. Click the "Enable" button on the C7-XR™ OCT System interface to allow the system to detect initiation of the imaging flush. The DOC 2.0™ drive motor will audibly speed up when the system is enabled for pullback initiation. The "Enabled" state lasts for 15 seconds.
4. Begin contrast media injection with automated power injector pump.
5. The OCT system and DOC 2.0™ will automatically initiate the rapid pullback of the imaging fiber within the Dragonfly™ Imaging Catheter.
6. When the OCT pullback length limit is reached (approx 3 seconds) the scan will stop. The OCT system saves the pullback file and then loads it for post-acquisition review. The OCT system will automatically advance the imaging catheter lens back to its original distal position following every pullback.
7. When all OCT imaging is complete, withdraw the Dragonfly™ Imaging Catheter into the guide catheter under fluoroscopic observation.
8. To disconnect the Dragonfly™ Imaging Catheter press the DOC 2.0™ "unload" button. Wait while the optical fiber disconnects internally, indicated by the DOC 2.0™ green light flashing. When the green light returns to steady state, gently twist the white catheter hub ¼ turn counter-clockwise and it will disengage from DOC2.0™.

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Regar E, Schaar JA, Mont E, Virmani R, Serruys PW (2003). Optical Coherence Tomography. Cardiovascular Radiation Medicine, 4: 198-204.

Figures

Figure 1: Dragonfly™ Imaging Catheter

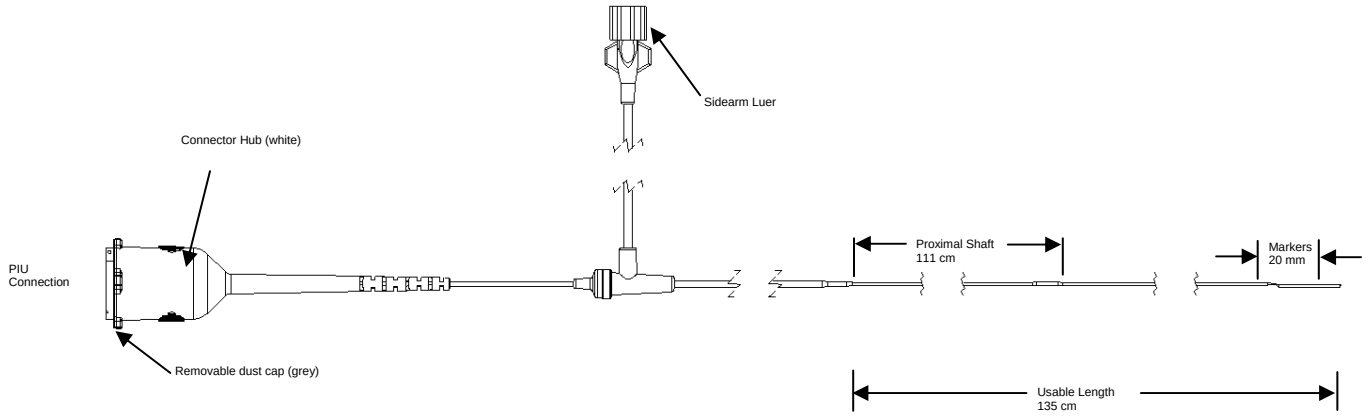
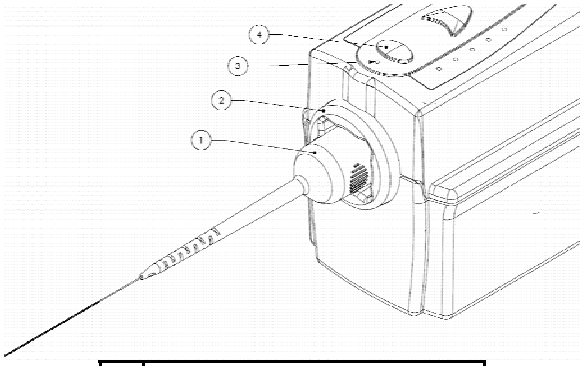
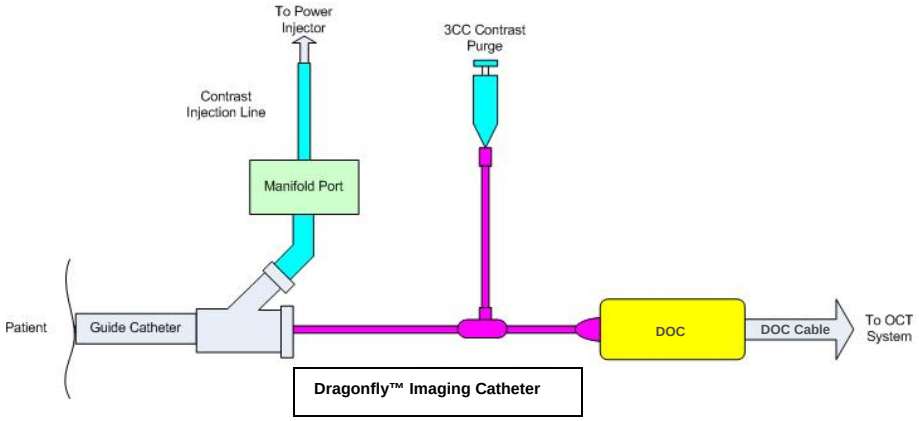


Figure 2: Imaging Catheter Connection to DOC 2.0™



1	ImageWire White Connector
2	DOC 2.0™ Black Port
3	DOC 2.0™ Green Indicator Light
4	DOC 2.0™ Unload Button

Figure 3: Connection Configuration



C7-XR™ OCT

Intravascular Imaging System

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ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

RX Only

Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Product referenced is approved for CE Mark.

Item 1000422216N

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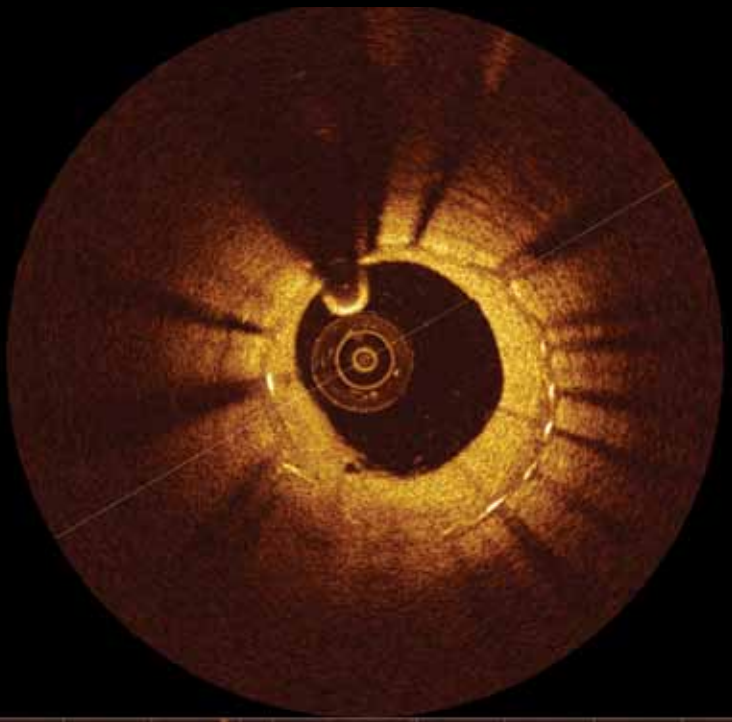
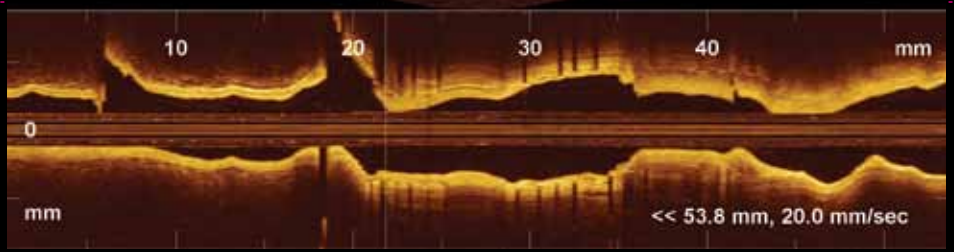
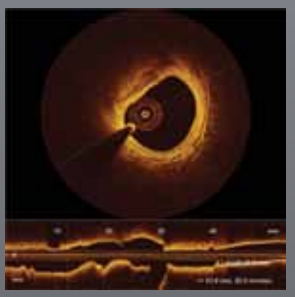


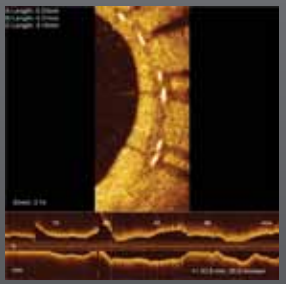


Assess Complex Lesions
WITH CONFIDENCE

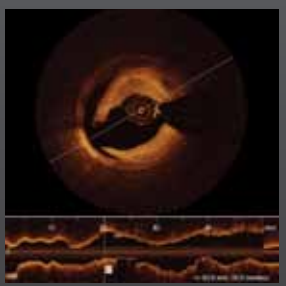
Optical Coherence Tomography (OCT) with Extreme Resolution™ provides unparalleled fast and accurate imaging. The C7-XR optimizes visualization for lesion assessment, treatment and follow-up strategies. The C7-XR intravascular imaging system optimizes evaluation and diagnoses.



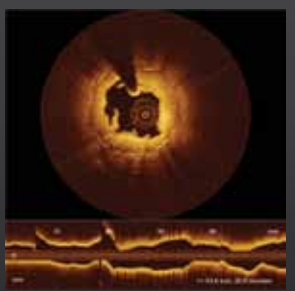
Calcium Deposit with Medial Diffusion[1]



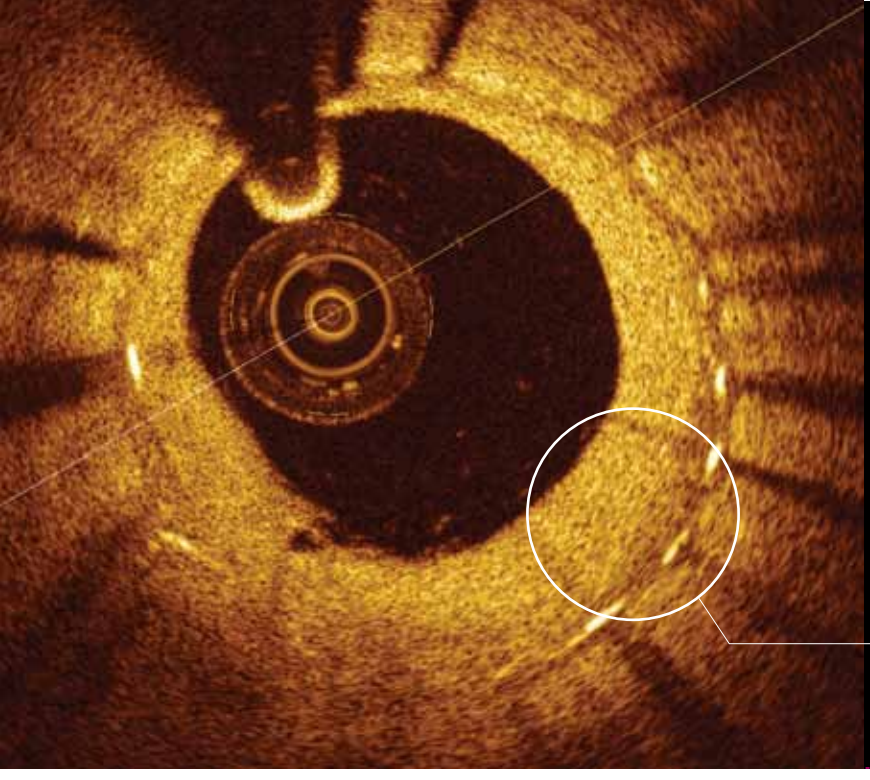
In-Stent Restenosis[2]



Edge Dissection



In-Stent Restenosis with Dissection[2]



C7-XR OCT IMAGING PROVIDES UNPRECEDENTED CONTROL

- Ultra-high resolution for easy visualization and clarity
- 100 Hz frequency for reduced or eliminated blurring
- Simplified assessment of complex lesions

Unprecedented Ability to Optimize Care

With resolution 10 times greater than IVUS[3,4,5], the C7-XR OCT enhances your ability to see it the first time – from stent placement to follow-up care.

- Measure reference segments
- Classify lesion morphologies
- Evaluate stent placement
- Differentiate and classify plaque[1]

Unprecedented Ease of Operation

The imaging procedure is fast and easy – retrieve real-time images in under 5 seconds. Rapid exchange catheter deployment eliminates exchanges, connections, tubing and accessories.

- Start the system and enter patient data
- Set up the catheter using automated calibration and automatic connection to the controller
- Initiate an automatic imaging pullback with a small contrast injection

Unprecedented Detail

Powerful analysis tools provide the ability to fine-tune assessments and customize care.

Unprecedented Technology

The C7-XR OCT is the only Extreme Resolution system for intracoronary imaging. Enhanced image quality and automated analysis functions provide an exceptional level of clear and detailed information.

SYSTEM COMPONENTS

- C7-XR frequency domain imaging engine and custom PC
- Two monitors (17” and 19”) plus remote video output
- Keyboard/mouse controls for system and catheter
- 22 x CD/DVD±RW dual layer DVD-RAM drive
- Large capacity hard drive
- HIPAA-compliant security features
- Integrated drive motor and optical controller (OC)

IMAGING SYSTEMS SPECIFICATIONS

System Dimensions

Size: 1430 (h) X 471 (w) X 683 (d) mm

Imaging Parameters

Maximum frame rate: 100 fps

Nominal pullback speed: 20 mm/sec

Lines per frame: 500

Scan diameter: 10 mm

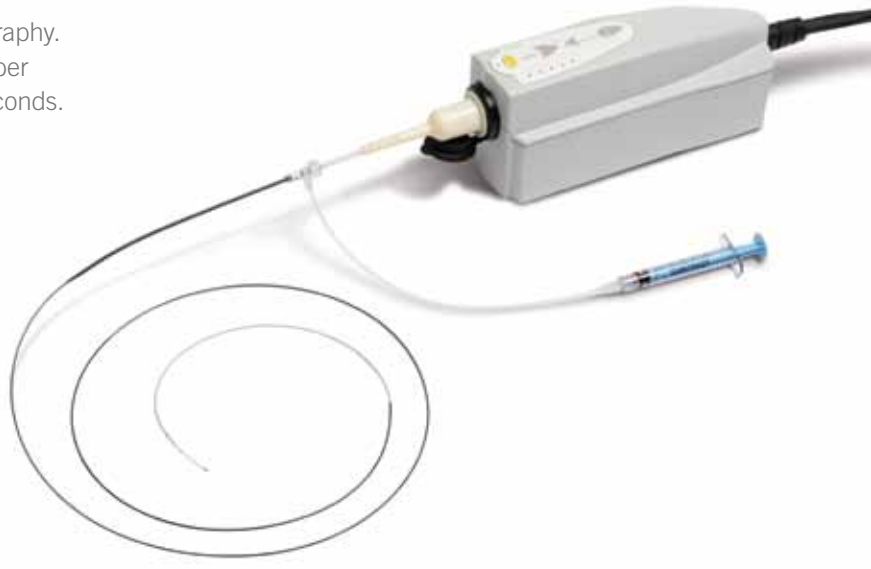
Axial resolution: 15 µm

Unprecedented Efficiency

The C7 Dragonfly imaging catheter uses Optical Coherence Tomography. This emits near-infrared light with a data sampling rate of 100 MB per second to produce real-time, high resolution images in under 5 seconds.

C7 DRAGONFLY IMAGING CATHETER

- Extreme Resolution imaging based on OCT technology
- Low-profile minirail tip for fast placement
- Hydrophilic coating reduces drag
- Dual marker bands for precise positioning
- Compatible with standard 0.014" steerable guidewires
- Imaging speed up to 25 mm per second



C7 DRAGONFLY IMAGING CATHETER SPECIFICATIONS

Usable length:
135 cm

Outer diameter:
2.7 F (distal)

Wire lumen:
0.014"

Committed to Interventional Cardiologists

St. Jude Medical is committed to delivering innovative tools and technologies to support and advance the practices of interventional cardiologists. The C7-XR OCT intravascular imaging system provides unprecedented image clarity to optimize assessment, treatment and follow-up strategies.

Ordering Information

C7-XR OCT Intravascular Imaging System

Contents: OCT Imaging Engine, LightLab Cardiology Application Software Package, Drive-motor & Optical Controller, C7-XR Fourier Computer, Operator's Monitor - High Resolution LED 17", Physician's Monitor - High Resolution LED 19", Integrated Mobile Cart, Keyboard & Mouse, Accessory Kit, Operator's Manual, and Essential's Guide (1 unit per box).

Reorder Number	Description
900-700-00	C7-XR™ OCT Imaging System

C7 Dragonfly Imaging Catheter

Kit Contains: C7 Dragonfly Imaging Catheter, Sterile DOC Cover, Sterile 3 ml Syringe (5 units per box)

Reorder Number	Length (cm)	Outer Diameter (distal)	Wire Lumen (in)	Coating
100-100-KT	0.014	2.7 F	0.014	Hydrophilic

Individual Items

Reorder Number	Description
100-100-00	C7 Dragonfly Imaging Catheter
200-700-00	Sterile DOC Cover
200-100-00	Sterile 3 ml Syringe

For more comprehensive intravascular lesion assessment, further optimize your PCI procedures with fractional flow reserve (FFR) technology. FFR:

- Evaluates functional severity of coronary lesions
- Relates lesion to maximum blood flow, collaterals and supplied myocardial mass
- Guides complex procedures for improved outcome and reduced costs[6]

Contact the St. Jude representative in your area or call 1.800.253.9073 to learn more about the OCT + FFR diagnostic solution.

References

1. Prati, F, Regar E, et al. Expert review document on methodology, terminology, and clinical applications of optical coherence tomography: physical principles, methodology of image acquisition, and clinical application for assessment of coronary arteries and atherosclerosis. *European Heart Journal.* 2010;31:401-415.
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4. J. Dijkstra, G. Koning & J.H.C. Reiber; Quantitative Measurements in IVUS Image. *International Journal of Cardiac Imaging* 15: 513-522, 1999.
5. Data on file at St. Jude Medical.
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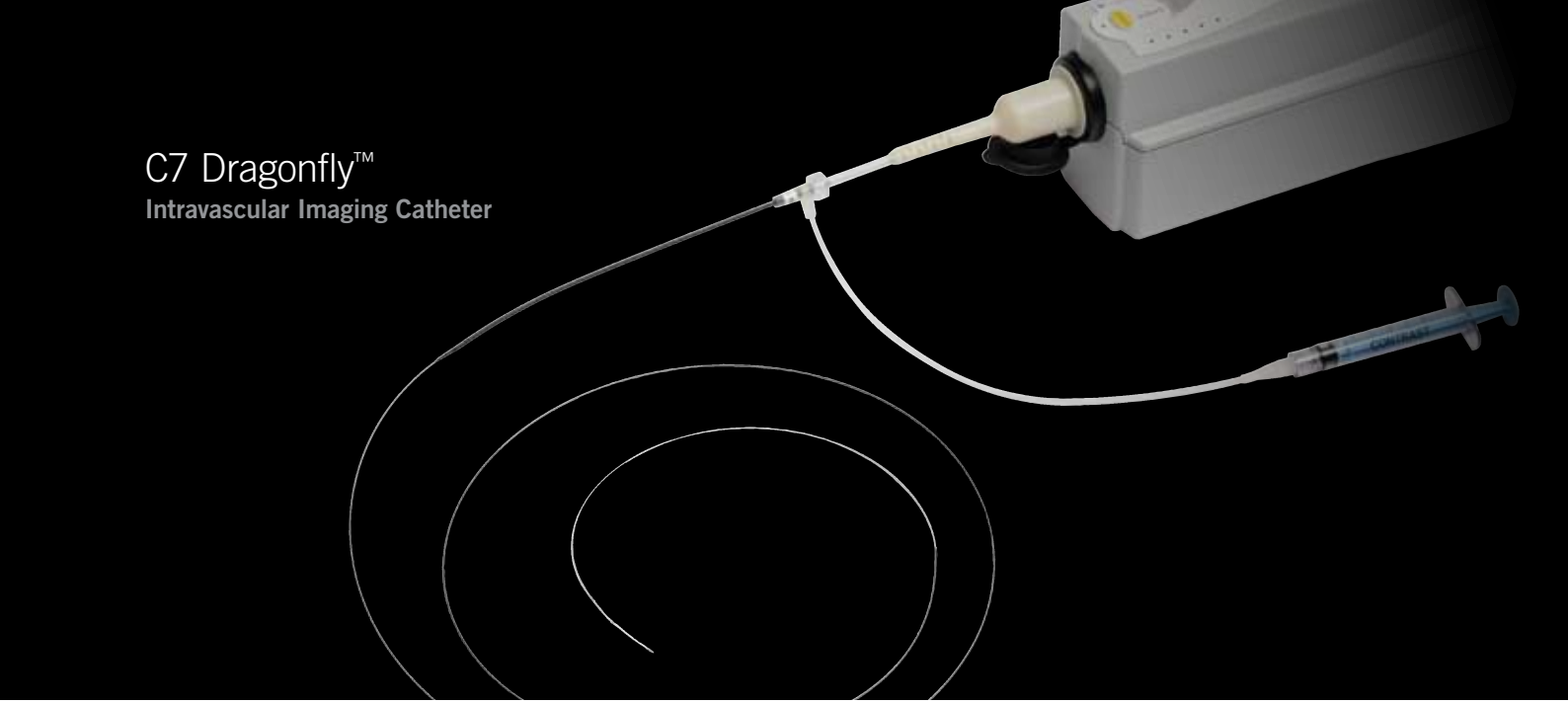
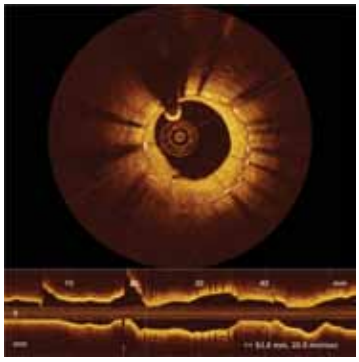


C7 Dragonfly™
Intravascular Imaging Catheter

Extreme Resolution.™
Confident Lesion Assessment.

The C7 Dragonfly catheter provides unprecedented magnification and detail in intravascular imaging. Using Optical Coherence Tomography (OCT), the C7 Dragonfly emits near-infrared light for a data sampling rate of 100 MB per second to produce real-time, ultra-high definition images. Combined with the C7-XR™ OCT intravascular imaging system, the C7 Dragonfly offers a new standard for lesion assessment, classification and diagnosis.

- Extreme Resolution imaging based on OCT technology
- Low-profile minirail tip for fast placement
- Hydrophilic coating reduces drag
- Dual marker bands for precise positioning
- Compatible with standard 0.014" steerable guidewires
- Imaging speed up to 25 mm per second



C7-XR OCT image – ten times better resolution than IVUS[1,2,3]

C7 DRAGONFLY IMAGING CATHETER

St. Jude Medical™
More control. Less risk.

Ordering Information

C7 Dragonfly Imaging Catheter (13751-02)

Kit Contains: C7 Dragonfly Imaging Catheter, Sterile DOC Cover, Sterile 3 ml Syringe (5 units per box)

Reorder Number	Length (cm)	Outer Diameter (distal)	Wire Lumen (in)	Coating
100-100-KT	0.014	2.7 F	0.014	Hydrophilic

Individual Items

Reorder Number	Description
100-100-00	C7 Dragonfly Imaging Catheter
200-700-00	Sterile DOC Cover
200-100-00	Sterile 3 ml Syringe

References

1. Steven E. Nissen and Paul Yock; Intravascular Ultrasound: Novel Pathophysiological Insights and Current Clinical Applications. *Circulation* 2001;103;604-616.
2. J. Dijkstra, G. Koning & J.H.C. Reiber; Quantitative Measurements in IVUS Image. *International Journal of Cardiac Imaging* 15: 513-522, 1999.
3. Data on file at St. Jude Medical.

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