ADVANCED UNIVERSITY POST GRADUATE COURSE

Fondazione

Ricerca e Innovazione

Cardiovascolare

### DRUG-COATED BALLOONS IN CORONARY AND PERIPHERAL INTERVENTIONS

SCIENTIFIC DIRECTORS: PROF. BERNARDO CORTESE PROF. GIUSEPPE MASSIMO SANGIORGI

SCIENTIFIC CO-DIRECTORS: DOTT.SSA DANIELA BENEDETTO DOTT. GIANLUCA MASSARO A HIGHLY SPECIALIZED UNIVERSITY COURSE FOCUSED ON EMERGING DRUG-COATED BALLOON TECHNOLOGY

UNIVERSITÀ DEGLI STUDI DI NAPOLI

FEDERICO II

ififi

A UNIQUE OPPORTUNITY FOR STUDENTS AND DOCTORS INTERESTED IN COMBINING SCIENTIFIC AND PRACTICAL KNOWLEDGE IN MEDICAL RESEARCH AND INTERVENTIONAL CARDIOLOGY







### PRESENTATION

Drug-coated or drug-eluting balloon (DCB, DEB) technology has emerged as an additional tool in the arsenal of interventional cardiology devices. These devices are capable of eluting antiproliferative drugs into the intima, media and adventitial tunica of the arterial wall through a single prolonged inflation of an angioplasty balloon. This strategy theoretically reduces the risk of a late inflammatory response to stent implantation without hindering positive vessel remodeling and distant vasomotility. DCBs, if used carefully and with good technique, can play a role in the treatment of different types of lesions, such as in-stent restenosis, and small vessel disease. Today the indications for the use of these devices are enormously increasing given the enormous potential advantages, primarily the reduction of dual anti-aggregating therapy, and include the treatment of bifurcations, long lesions, total chronic occlusions. Furthermore, hybrid procedure techniques (spot stenting and drugcoated balloon) are emerging as an excellent alternative to multiple stent implantation. Given the growing interest that this technology is gathering in various clinical specialties, together with its potential impact on doctors, patients and stakeholders in the sector, this highly specialized course on DCBs aims to be a moment to discuss with teachers the clinical effectiveness and DCB safety, highlight the latest innovations and advances in the field and simultaneously identify challenges and opportunities for future development.







### **TRAINING OBJECTIVE**

The use of Drug-Coated Balloons is a rapidly growing field of research in medicine. These devices offer an innovative and promising way to administer drugs in a targeted and controlled manner to the patient, minimizing side effects and maximizing therapeutic efficacy. A highly specialized university course focused on this emerging technology represents a unique opportunity for students and doctors interested in combining scientific and practical knowledge in medical research and interventional cardiology.

One of the main objectives of the high-specialty course on Drug-Coated Balloons is to provide learners with a solid theoretical and practical foundation of knowledge in several related fields, such as medicinal chemistry, materials engineering, pharmacology, and biotechnology. This will allow learners to understand the physical and chemical properties of the materials used to produce the medicated balloons, as well as the interactions between drugs and the human body.

The different types of Drug-Coated Balloons on the market will be discussed to understand how the elution of different drugs is influenced by the excipients, and carriers and how the drug is linked to the balloon until its inflation.

Another important aspect of the Master is to provide students with practical and in-depth training in the field of their use with lessons in the various clinical-interventional settings, both coronary and peripheral, also having the opportunity to attend live interventions to discuss the various therapeutic and advanced imaging strategies that can be used with this technology to evaluate the immediate result and the management of any complications.







### **TRAINING OBJECTIVE**

Furthermore, the course will provide information for performing an angioplasty with a drug balloon as recommended by experts in the field, highlighting how it must be performed differently from how a stent is implanted and will provide indications on the use of preparation and debulking before applying the medicated balloon itself.

Another crucial aspect of the Master is to encourage research and innovation in the field of Drug-Coated Balloons. Learners can actively participate in research projects, working closely with teachers and researchers in the field. Students will acquire various knowledge regarding the production and characterization techniques necessary to develop medical balloons, and comparison and collaboration with the industrial sector will be strongly encouraged to transfer scientific developments into concrete clinical applications.

Finally, the Master Course will allow learners to understand the challenges related to the safety, quality, and regulation of medical balloons and develop knowledge of health policies related to their use. This type of critical awareness would prepare students to tackle complex challenges in the industry and contribute to more effective rules and regulations in the field of medical balloons.

In conclusion, a Master in Drug-Coated Balloons would represent a unique opportunity for students to acquire specialized skills and knowledge in one of the most promising areas of medical research.

Through a combination of theoretical and practical training, the highly specialized course will prepare learners for using this technology in interventional cardiology, offering a potentially improved solution for treating coronary and peripheral atherosclerotic diseases.







### **WHO IS FOR?**

The Advanced University Post-graduate Course on Drug-Coated Balloons in Coronary and Peripheral Interventions is aimed at cardiologists, vascular surgeons, and interventional radiologists who want to deepen their theoretical-practical knowledge of this new technological field.

Therefore, the Course is open to candidates with a degree in Medicine and Surgery and a specialization diploma (or equivalent qualification) in Cardiology, Vascular Surgery, Radiology, or similar disciplines. Those who do not yet have a specialization diploma and who will obtain the title before the end of the Master Classes can be admitted with reservations.







PTV

### **PURPOSES AND PROFESSIONAL PROFILES**

The Course has an interdisciplinary approach aimed at increasing skills in the various disciplinary areas involved in the management of patients suffering from coronary and peripheral atherosclerosis. In particular, the general objective is to provide learners with the theoretical and practical elements for an innovative and modern therapeutic approach to the patient suffering from this problem.

Specifically, the High Specialization Course aims at:

- Providing the diagnostic bases and clinical criteria that allow identifying patients potentially susceptible to percutaneous approaches with medicated balloons and/or hybrid techniques
- Providing the anatomical-pathological basis to understand the correct functioning of this technology
- Providing chemical-pharmaceutical notions to show how the use of different excipients, carriers, nano-carriers, and adhesion techniques of the drug on the balloon change the effectiveness of its us
- Illustrating the panorama of imaging techniques, their interpretative bases, and their use in the diagnostic-therapeutic process
- Analyzing the pre-, intra-, and post-operative medical aspects
- Illustrating, both theoretically and practically, the novelties of endovascular interventional techniques for treatment (medicated balloons, imaging and debulking techniques)
- Providing elements of health economics and resource management with a focus on the socio-economic impact of this innovative approach in medicine.





# TEACHING MODE AND STRUCTURE

The educational path is developed in 4 stages of two days each (Friday half day; Saturday full day) according to a structure that includes educational activities consisting of remote classroom training and diagnostic-interventional training through live cases and live-in-thebox cases.

Recordings of surgical operations will be uploaded online to a specific electronic platform, which the learner can view in "Live in the Box" mode.

According to the indications provided by the scientific directors at the beginning of the course, the practical internship will be held under the aegis of the University School and the Department of Biomedicine and Prevention of Tor Vergata University.

There will be frontal online lessons and practical learning from the Cath Lab for imaging utilization during Drug-Coated Balloon applications. Lesions preparation with SC and NC plain old balloon angioplasty will be discussed. Techniques for DCB utilization will be shown in different clinical scenarios.

Furthermore, free participation in the "Drug Eluting Balloon Stories-DEBS" Congress which will be held in Rome, at the NH Vittorio Hotel on 30-31 January 2025, is also envisaged for all those enrolled in the Course. The books "Drug-Coated Balloons" Applications in Interventional Cardiology 1st and 2nd Edition," edited by Prof. Bernardo Cortese, will also be provided free of charge for deeper scientific knowledge of Learners.







# TEACHING MODE AND STRUCTURE

Classroom training will be divided into the following disciplinary areas:

- Interventional treatments aimed at acquiring advanced knowledge, technical and management skills of percutaneous intervention
- Imaging: aimed at acquiring the interpretative bases of the main imaging techniques to optimize the pre-surgery diagnostic process and post-operative management
- Health Management: aimed at analyzing innovative techniques' economic, socio-health, and cost-effective aspects.

The teaching material provided by the teachers (video-recorded material in .pdf format), protected by copyright, will be uploaded to the Mooxi Srl secretariat platform. Students' access to the teaching material is guaranteed by personal access credentials.

At the end of each internship, a written multiple-choice test verifies the knowledge acquired. To obtain the university certificate and the related credits, the learners must pass ongoing tests and final multiple-choice questions and discuss a final paper.







# TEACHING MODE AND PROGRAM

- Online frontal training distributed over 5 monthly period of 2 days each, 15 hrs for each month
- Free subscription and participation at the DEBS congress in Roma-January 2025
- Free books Drug-Coated Ballon 1st and 2nd edition, by Prof. Cortese
- Voluntary Internship in the Cath Lab operating rooms for observation during interventions at the Cardiology and Vascular Surgery Sections of the University of Tor Vergata.







LESSONS WILL BE HELD ON FRIDAY FROM 13.00 TO 18.00 AND SATURDAY FROM 09.00 TO 18.00

#### **1ST STAGE**

#### 27-28TH SEPTEMBER 2024

TEACHING MACRO-AREAS: DCBS HISTORY, EUROPEAN AND ITALIAN DCBS MARKET, PHARMACOLOGY AND CHEMICAL ASPECTS OF DCBS

#### FRIDAY SEPTEMBER 27TH 2024

#### TIME TABLE

13.00-13.30	WELCOME AND COURSE INTRODUCTION	BERNARDO CORTESE, GIUSEPPE SANGIORGI
13.30-14.30	BRAINSTORMING FOR THESIS ASSIGNMENT	BERNARDO CORTESE, GIUSEPPE SANGIORGI
14.30-15.00	FROM DRUG ELUTING TO DRUG COATING BALLOONS	BERNARDO CORTESE, GIUSEPPE SANGIORGI
15.00-15.30	HISTORY OF DRUG ELUTING BALLOON	DANIELA BENEDETTO
15.30-16.00	DCB ARC CONSENSUS DOCUMENTS: MY PERSPECTIVE AND STATE OF THE ART IN THE FACE OF CONTROVERSY	DANIELA BENEDETTO
16.00-16.30	EUROPEAN GUIDELINES FOR DCB UTILIZATION IN CORONARY AND PERIPHERAL INTERVENTIONS: WHAT IS NOT THERE TO GET	DANIELA BENEDETTO
16.30-17.00	DCB IN ITALY: THE GISE DATA	GIUSEPPE SANGIORGI
17.00-17.30	LIVE IN THE BOX	BERNARDO CORTESE
17.30-18.30	LIVE CASE	DANIELA BENEDETTO







#### SATURDAY SEPTEMBER 28TH 2024

#### TIME TABLE

9.00-10.00	TECHNICAL INSIGHT ON DRUG COATED BALLONS	BERNARDO CORTESE
10.00-10.30	GENERAL ENGINEERING	ENGINEER 1
10.30-11.00	GENERAL ENGINEERING	ENGINEER 2
11.00-11.30	WE TAKE BEST FROM BOTH MICROCRYSTALLINE FORMULATION	JUAN GRANADA
11.30-12.30	2 LIVE IN THE BOX	BERNARDO CORTESE
14.30-15.00	GENERAL ENGINEERING	ENGINEER 3
16.00-16.30	GENERAL ENGINEERING	ENGINEER 4
16.30-17.00	GENERAL ENGINEERING	ENGINEER 5
17.00-18.00	LIVE IN THE BOX	DANIELA BENEDETTO







#### 2ND STAGE

#### OCTOBER 25,26TH 2024

TEACHING MACRO-AREAS: DCB HISTOPATHOLOGY, DRUG-DYNAMIC AND CHEMICO-PHYSICAL ELUTION, ASPECTS IN DCB, COATING ED EXCIPIENTS, LESION PREPARATION, IMAGING DURING DCB UTILIZATION

#### FRIDAY, OCTOBER 25TH 2024

#### TIME TABLE

13.00-13.30	DOES ONE DCB FIT ALL? PATHOLOGIC DIFFERENCES COMPARED TO LAST GENERATION DES	GIUSEPPE SANGIORGI
13.30-14.00 	LESION PREPARATION: HOW TO DO IT AS BEST AS POSSIBLE	BERNARDO CORTESE,
14.00-14.30 	ACUTE RECOIL AND DISSECTION MANAGEMENT AFTER DCBS- HOW TO OVERCOME FEAR?	GIUSEPPE SANGIORGI
14.30-15.30	CUTTING, SCORING, AND OTHER DEBULKING TECHNIQUES BEFORE DCB: A SMART OPTION TO IMPROVE LONGETERM OUTCOME?	DANIELA BENEDETTO
15.30-16.00	IMAGING FOR DCB: MY EYES ARE WIDE OPEN, AND I'LL TELL YOU WHY IT'S ESSENTIAL	JOSÉ MARÍA DE LA TORRE HERNÁNDEZ
	LIVE IN THE BOX	GIULIO RUSSO
17.00-18.00	LIVE CASE	GIANLUCA MASSARO







#### SATURDAY 26 OCTOBER 2024

#### TIME TABLE PROGRAM PATHOLOGY OF DCB 9.00-10.00 ALOKE FINN ANIMAL MODELS IN DCB SCIENCE JUAN GRANADA 10.00-11.00 REAL-WORLD USAGE OF DRUG-COATED BALLOONS EXCEEDS **BERNARDO CORTESE** 11.00-12.00 GUIDELINE RECOMMENDATIONS. WHICH STUDIES WE NEED TO FILL THIS CAP? ARE THERE STILL LIMITATIONS IN DCB TREATMENT COMPARED TO 12.00-13.00 **GIUSEPPE SANGIORGI** DES ACCORDING TO STUDIES? ...... ANTIPLATELET THERAPY AFTER DCB: SHORTER OR MARCO VALGIMIGLI 15.30-16.00 EOUAL TO "BEST IN CLASS" DES? NEW TREATMENT HORIZONS DRIVEN BY NEW STUDIES 16.00-16.30 ANDREA MORETTI AND REGISTRIES LIVE IN THE BOX DANIELA BENEDETTO 16.30-17.00 17.00-18.00 **GIANLUCA MASSARO** LIVE CASE WITH OCT





**3RD STAGE** 

NOVEMBER 29, 30TH 2024

TEACHING MACRO-AREAS: DCB'S CLINICAL INDICATIONS IN DIFFERENT CORONARY AND PERIPHERAL SCENARIOS

#### FRIDAY, NOVEMBER 29TH 2024

	T	<b>^</b>	- 1	
			_	_

13.00-13.30	DRUG COATED BALLOONS FOR ISR	FERNANDO ALFONSO
 13.30-14.00	DRUG COATED BALLOONS FOR SMALL VESSEL DISEASE	JOSÉ MARÍA DE LA TORRE HERNÁNDEZ
 14.00-14.30	DRUG COATED BALLOONS FOR BIFURCATION	ALFREDO MARCHESE
14.30-15.30 	DRUG COATED BALLOONS FOR DIFFUSE DISEASE	LUCA TESTA
15.30-16.00	DRUG COATED BALLOONS FOR DIABETIC	GIUSEPPE MUSUMECI
 16.00-16.30	DRUG COATED BALLOONS FOR HIGH BLEEDING RISK PATIENTS	UGO LIMBRUNO
 16.30-17.00	DRUG COATED BALLOONS FOR ACUTE CORONARY SYNDROME	SIMON ECCLESHALL
17.00-18.00	LIVE CASE	BERNARDO CORTESE







#### SATURDAY, NOVEMBER 30TH 2024

#### TIME TABLE

9.00-9.30	DCB MORTALITY IN PERIPHERAL INTERVENTION	THOMAS ZELLER
9.30-10.00	DRUG COATED BALLOON FOR SFA ISR	ANTONIO MICARI
10.00-10.30	DCB AND ADJUNCTIVE TREATMENT FOR NATIVE SFA DISEASE	EUGENIO STABILE
11.00-11.30	DCB FOR PROXIMAL SEGMENT BELOW THE KNEE DISEASE, OR IT:S TIME ALSO FOR DISTAL?	ROBERTO FERRARESI
11.30-12.00	DOES DCB MAY HOLD PROMISES ALSO IN CRITICAL LIMB ISCHEMIA TREATMENT?	FRANCESCO LISTRO
12.00-12.30	AVF MANAGEMENT: HOW DCB IMPACT ON CLINICAL RESULT	MARCO FRANCHIN
14.00-15.30	RATIONAL AND CLINICAL RESULTS OF DCB UTILIZATION IN VASCULOGENIC ERECTILE DYSFUNCTION	GIUSEPPE SANGIORGI
15.30-16.00	LIVE IN THE BOX	FLAVIO AIROLDI
16.30-17.00	LIVE CASE	MARCO MANZI
17.00-18.00	LIVE CASE	STEFANO FAZZINI







**4TH STAGE** 

**JANUARY 30TH, 31ST 2025** 

PARTICIPATION IN THE DRUG ELUTING BALLOON STORIES CONGRESS 2025, ROME

**5TH STAGE** 

FEBRUARY 28TH, MARCH 1ST 2025

TEACHING MACRO-AREAS: REGULATION ASPECTS, DEBS' REFUND, UTILISATION IN THE REAL WORLD

#### FRIDAY, FEBRUARY 28TH 2025

TIME TABLE

#### PROGRAM

13.00-13.30	COST-EFFECTIVENESS AND REIMBURSEMENT POLICY	BHARAT KHIALANI
13.30-14.00	REGULATORY ASPECTS WITH DCBS	ABBOTT REGULATORY
14.00-14.30	DCBS IN WOMAN	PIERPASQUALE LEONE
14.30-15.00	DRUG COATED BALLOONS IN REAL WORLD	GIUSEPPE TARANTINI
15.00-15.30	DCB AND POSITIVE REMODELING	GIUSEPPE SANGIORGI
15.30-16.00	WHY DCB AND NOT DES? DID YOU EVER THINK ABOUT DES LIMITATIONS?	MICHAEL JONER
16.00-16.30	DCB FOR LARGE VESSELS	ALESSANDRO SCIAHBASI
16.00-17.00	DEB AND CTO	ROBERTO GARBO
17.00-18.00	LIVE IN THE BOX	GIUSEPPE SANGIORGI

SATURDAY, MARCH 1ST 2025

TIME TABLE

PROGRAM

9.00-12.00

THESIS DISCUSSION





ALOKE FINN CARDIOLOGY, UNIVERSITY OF MARYLAND, USA

**ROBERTO FERRARESI** CARDIOLOGY. CLINICA

**DUGNANO, MILANO** 

**UGO LIMBRUNO** CARDIOLOGY, OSPEDALE DI GROSSETO

CARDIOLOGY. OSPEDALE DI GROSSETO

SAN

CARLO

DI

PADERNO

PIERPASQUALE LEONE CARDIOLOGY, MOUNT SINAI HOSPITAL, NYC, US

TAN TOCK SENG HOSPITAL. SINGAPORE

CARDIOLOGY, COLUMBIA UNIVERSITY, USA

JUAN GRANADA

**BHARAT KHIALANI** 

**MICHAEL JONER** 

FRANCESCO LIISTRO

**ROBERTO GARBO** CARDIOLOGY, MARIA PIA HOSPITAL, TORINO

SURGERY. AZIENDA

**MARCO FRANCHIN** SOCIO SANITARIA TERRITORIALE SETTE LAGHI. VARESE



Fondazione

Ricerca e Innovazione

Cardiovascolare

B

AL ACADEMY



**FERNANDO ALFONSO** CARDIOLOGY, HOSPITAL UNIVERSITARIO LA PRINCESA. MADRID - SPAIN

DANIELA BENEDETTO CARDIOLOGY, POLICLINICO TOR VERGATA ROMA

**BERNARDO CORTESE** CARDIOLOGY, UNIVERSITY HOSPITAL, CLEVELAND, US

JOSÉ MARIA DE LA TORRE HERNANDEZ CARDIOLOGY, HOSPITAL UNIVERSITARIO MAROUÉS DE VALDECILLA, SPAGNA

**STEFANO FAZZINI** VASCULAR CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI **ROMA TOR VERGATA** 

CARDIOLOGY, HEART CENTRE, MUNICH-GERMANIA

VASCULAR







FEDERICO II

MARCO MANZI RADIOLOGY, POLICLINICO ABANO TERME

ALFREDO MARCHESE CARDIOLOGY, VILLA ANTEA, BARI

GIANLUCA MASSARO CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI ROMA, TOR VERGATA

GIUSEPPE TARANTINI CARDIOLOGY, UNIVERSITÀ DI PADOVA

ANTONIO MICARI CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI MESSINA

ANDREA MORETTI CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI ROMA TOR VERGATA

GIUSEPPE MUSUMECI CARDIOLOGY, OSPEDALE MAURIZIANO, TORINO

GIULIO RUSSO CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI ROMA, TOR VERGATA GIUSEPPE M. SANGIORGI CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI ROMA TOR VERGATA

ALESSANDRO SCHIAHBASI CARDIOLOGY, OSPEDALE PERTINI, ROMA

EUGENIO STABILE CARDIOLOGY, OSPEDALE SAN CARLO, POTENZA

GIUSEPPE TARANTINI CARDIOLOGY, UNIVERSITÀ DEGLI STUDI DI PADOVA

LUCA TESTA CARDIOLOGY, OSPEDALE SAN RAFFAELE, MILANO

TJUN TANG VASCULAR SURGERY, VASCULAR AND ENDOVASCULAR CLINIC, SINGAPORE

MARCO VALGIMIGLI CARDIOLOGY, CARDIOCENTRO TICINO, LUGANOM SVIZZERA

THOMAS ZELLER ANGIOLOGY, HERZZENTRUM FREIBURG, BAD KROZINGEN, GERMANY.

RAOUL SAGGINI PHYSIATRY AND REHABILITATION, UNIVERSITÀ DEGLI STUDI ECAMPUS







### ORGANIZING SECRETARIAT AFFILIATED WITH THE UNIVERSITY

MOOXI SRL PIAZZA GIROLAMO FABRIZIO, 6 / 00161 ROMA (RM) P.IVA: 14964251004 CELL: 3342220627 E-MAIL: MOOXISRLFORMAZIONE@GMAIL.COM

SUPPORTING SECRETARIAT: ASSOCIAZIONE ECU-EDUCAZIONE CONTINUA UNIVERSITARIA

### **ENROLMENT METHOD**

IN ORDER TO ENROL THE COURSE, IT IS NECESSARY TO SEND TO THE EMAIL ADDRESS MOOXISRLFORMAZIONE@GMAIL.COM ALL THE FOLLOWING DOCUMENTS:

- DEGREE DIPLOMA (OR SELF-CERTIFICATION);
- SPECIALIZATION DIPLOMA;
- IDENTITY DOCUMENT CURRENTLY VALID (FRONT/BACK);
- HEALTH INSURANCE CARD AND FISCAL CODE (FRONT/BACK);
- ENROLMENT FORM (TO BE ASKED TO THE ORGANIZING SECRETARIAT MOOXI SRL)
- THE ENROLMENT IS TO BE INTENDED AS COMPLETED AS WRITTEN ABOVE. THERE WILL BE NO ENROLMENT OR SELECTION TEST.

