

GENERAL DATA

Center

E001 Patient's Initials : , (First, Last) E002 Sex M F

E003 Admis. day date E004 Time hrs min

E005 Date of birth dd mm yy

E006 Angioplasty Date E007 Time hrs min

Morphology:

E008 Target lesion \geq 14 mm in length? Y N

E009 Chronic total occlusion Y N

E010 Restenosis? Y N

E011 Target lesion is in a saphenous vein graft? Y N

If yes in any of the previous question E006-E009, EXCLUSION

E012 Ostial target lesion? Y N

E013 Evidence of intracoronary thrombus? Y N

E014 Contraindication to oral antiplatelet therapy (ASA/Ticlopidine)? Y N

E015 Acute myocardial infarction (<12 hours)? Y N

E016 Acute myocardial infarction (<15 days)? Y N

E017 Stable angina *CCS classification* I II III IV

E018 Unstable angina *Braunwald classification* I II III OA OB OC
 O1 O2 O3

E019 Other indications: _____

Lesion:

E020 CAD: I II III Stable ischemia Unstable ischemia

E021 Treated vessel: RCA RCX LAD

E022 Stenosis: Visual % QCA % Other (specify) % _____

E023 Lesion length: mm

E024 Lesion type: A B1 B2 C

E025 Vessel diameter: , mm

E026 Tortuos vessel? Y N

E027 Calcification Mild Moderate Severe N

E028 Indication for stenting _____

Procedure:

E029 Predilatation performed (refer to Study Protocol) Y N

E030 Dissection? Y N

E031 Classification (specify): _____

E032 Number of stents:

E033 Type (if not Coroflex): _____

E034 Other stents in same vessel? (if Yes exclusion) Y N

E035 Stent deployment pressure: atm

E036 Stent size (mm): 2,5 3,0 3,5 4,0

E037/038 Inflation period: MAX Total

E039 Inflation number:

E040 Stent serial number:

E041 Maximal size of balloon used: , mm

E042 Postdeployment dilatation pressure: atm

E043 Residual stenosis: Visual % OCA % Other (specify) % _____

E044 Succesfull stent positioning? Y N

E045 CK following stenting: 6-8 h 10-14 h 20-24 h

E0046 Max CK ≤ 24h

Comedication:

E047 Ticlopidine/Clopidogrel: mg/day

E048 Heparin: I.U.

E049 ASA: mg/day

E050 Reo Pro:

E051 Others: _____

E052 Dose: mg/day

Handling Assessment:

E053 Stendis location from balloon catheter? Y N

E054 Radiopacity: Good Average Low

E055 Flexibility: Good Average Low

Outcome	Acute	Date
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E056		Date discharge	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E057	Bleeding or other local complications? <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="checkbox"/> Y <input checked="" type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E059	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E060	Comment: _____		
E061	Angina Pectoris symptoms?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E063	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E064	Comment: _____		
E065	Subacute thrombotic occlusion?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E067	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E068	Comment: _____		
E069	Myocardial infarction?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E071	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E072	Comment: _____		
E073	Emergency PTCA?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E075	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E076	Comment: _____		
E077	Bypass-OP?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E079	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E080	Comment: _____		
E081	Death?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}
E083	Caused by stent implantation?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	
E084	Comment: _____		
E085	Other major complication? (specify) _____		

E0086 Follow up type: Phone system patient referring physician
 Clinical examination in the center performing initial PTCA

Outcome	6 Months	Date
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E0087 Angina Pectoris symptoms? Y N E0088 ^{dd} ^{mm} ^{yy}

E0089 CCS 0 1 2 3 4

E0090 Caused by stent implantation? Y N

E0091 Comment: _____

E0092 Subacute thrombotic occlusion? Y N E0093 ^{dd} ^{mm} ^{yy}

E0086 Caused by stent implantation? Y N

E0094 Comment: _____

E0095 Myocardial infarction? Y N E0096 ^{dd} ^{mm} ^{yy}

E0097 Caused by stent implantation? Y N

E0098 Comment: _____

E0099 Emergency PTCA? Y N E100 ^{dd} ^{mm} ^{yy}

E0095 Caused by stent implantation? Y N

E0096 Comment: _____

E101 Bypass-OP? Y N E102 ^{dd} ^{mm} ^{yy}

E0099 Caused by stent implantation? Y N

E103 Comment: _____

E1014 Death? Y N E105 ^{dd} ^{mm} ^{yy}

E103 Caused by stent implantation? Y N

E106 Comment: _____

E107 Treadmill test performed? Y N E108 ^{dd} ^{mm} ^{yy}

E109/110/111 Ischemia W/min Pressure mm/Hg FC mm/Hg

E112/113/114 Angina W/min Pressure mm/Hg FC mm/Hg

E115/116/117 Max work load attained W/min Pressure mm/Hg FC mm/Hg

E118 Clinical Restenosis at 6 Months: Y N

E119 Comment: _____

E120 Angiographic follow-up: Y N

E121 If yes, degree of Visual % QCA % Other (specify) %

E122 Probably further interentions associated with stent implantation? Y N

E123 If yes, please describe: _____

CRF

ESTATE

Do **ES** the design of the s**T**ent ends influence
the **A**cute and long **TE**rm clinical result?

Postmarketing Surveillance
Evaluation of the Stent Design on the Safety
of the Coroflex Coronary Stent

Contact Point

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E O24 Lesion type

- | | | |
|----------------------------|---|--|
| Type A: | <ul style="list-style-type: none"> - Discrete (< 10 mm length) - Concentric - Readily accessible - Nonangulated segment, < 45° - Smooth contour | <ul style="list-style-type: none"> - Little or no calcification - Less than totally occlusive - Not ostial in location - No major branch involvement - Absence of thrombus |
| Type B₁: | <ul style="list-style-type: none"> - Tubular (10 to 20 mm length) - Eccentric - Moderate tortuosity of proximal segment - Moderately angulated segment, < 45°, < 90° - Irregular contour | <ul style="list-style-type: none"> - Moderate to heavy calcification - Total occlusion < 3 month old - Ostial in location - Bifurcation lesions requiring double guide wires - Some thrombus present |
| Type B₂: | Presence of two Type B characteristic in the same lesion. | |
| Type C: | <ul style="list-style-type: none"> - Diffuse (> 2 cm length) - Excessive tortuosity of proximal - Extremely angulated segments > 90% | <ul style="list-style-type: none"> - Total occlusion > 3 month old - Inability to protect major side branches - Degenerated vein grafts with friable lesions |

E031 Dissection NHLBI classification

Dissection type	Description	Angiographic Appearance
A	Minor radiolucencies within the coronary lumen during contrast injection with minimal or no persistence after dye clearance.	
B	Parallel tracts or double lumen separated by a radiolucent area during contrast injection with minimal or no persistence after dye clearance.	
C	Extraluminal cap with persistence of contrast after dye clearance from the coronary lumen.	
D	Spiral luminal filling defects.	
E +	New persistent filling defects.	
F +	Those non-A-E types that lead to impaired flow or total occlusion.	

+ May represent thrombus

E097 Bleeding or other local complications

MILD= - No interventions required
 - No prolonged hospital stay

MODERATE= - Minor interventions required
 - prolonged hospital stay

SEVERE= - Surgery required
 - Blood transfusion required

CRF - Sending instructions

- ✓ Pages A and B to be sent by fax (+39 0432 478686) within 2 days since discharge
- ✓ Pages C and D to be sent by fax (+39 0432 478686) at conclusion of F.U. (6 months)
- ✓ All CRFs (original copy) to be sent by mail at the end of the study