Form Name	Community
Study Essential Documents	CAVI C1503 BIOSOLVE-IV Version 9.0

Study Essential Documents

Site Initiation

Initiation Details

* = mandatory fields

BIOTRONIK Site ID *
site_id_bio

Name of Principal Investigator *
site_PI_name

Intent to Participate Declared
site_study_intent_part

Initiation Package Sent
site_study_init_pack_sent

Regulatory Binder Sent
site_study_reg_binder_sent

Regulatory Binder Recipient
site_study_reg_binder_recd

Clinical Study Agreement Signed
site_study_agreement_sign

Product Release Approval
site_study_prod_rel_approve

Approved to Enroll *
site_study_approve_enrol

Site Status *
site_study_site_status

Collection of time of IC required for this site * ○ Yes ○ No
site_study_time_of_ic

Tick checkbox if site is a pre-market site ☐ Pre-market site
site_study_pre_market

Study ID (C or G number)

Study ID (C- or G-number) *
studyid

If satellite: specify satellite name
satname

CIP Activation Dates for Site

Subjects enrolled on or after a "Date CIP v X.0 activated" will be flagged with the corresponding CIP version number on the enrolment form. As long as no CIP activation date is entered ere, the default is CIP v 1.0.

For CIP versions that were never relevant for a site please enter the same data as for the relevant version.

Date CIP v 2.0 activated
site_CIPv2_date

Date CIP v 3.0 activated
site_CIPv3_date

Date CIP v 4.0 activated
site_CIPv4_date

Version of eCRF

Enter current eCRF version and release date

V *
site_ecrfvers

Date *
site_ecrfdtc

site_study_site_status - Site Status * - 100845

Choice Text | Encoded Value

Start Up/Initiation | 1
Enrolling & Follow-up | 2
Follow-up Only | 3
Data Frozen | 4
Data Locked | 5

site_study_time_of_ic - Collection of time of IC required for this site * - 102622

Choice Text | Encoded Value

Yes | 1
No | 0

Form Name	Community
Enrolment	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Enrolment

Study ID [ ] CIP version [ ] eCRF version [ ]
enstudyid encipv ecrfvers

Current visit is [ ]
visit

Enrolment

* = field must be completed

Date of informed consent * [ ]
endtc

Time of informed consent * Time (24hr): [ ] [ ]
entim

Age at time of enrolment * [ ] years
age

Gender *
- Male
- Female

sex

sex - Gender * - 101853

Choice Text | *Encoded Value*

Male | 1

Female | 2

Form Name	Community
Inclusion/Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Inclusion/Exclusion Criteria
Inclusion Criteria

Current visit is
visit

Inclusion/Exclusion Criteria

Inclusion Criteria

1. Subject is ≥ 18 years of age — Yes No incl01

2. Subject must be willing to sign a Patient Informed Consent (PIC) or Patient Data Release Form (PDRF) where applicable. — Yes No incl02

3. Symptomatic coronary artery disease — Yes No incl03

4. Subject with a maximum of two single de novo lesions in two different major epicardial vessels — Yes No incl04

5. Target lesion length ≤ 21 mm by QCA or by visual estimation — Yes No incl05

6. Target lesion stenosis by visual estimation: > 50% - < 100% and TIMI flow ≥1 — Yes No incl06

7. Subject is eligible for Dual Anti Platelet Therapy (DAPT) — Yes No incl07

Form Name	Community
Inclusion/Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

Exclusion Criteria

Exclusion Criteria

1. Pregnant and / or breast feeding females or females who intend to become pregnant during the time of the registry — ○ Yes ○ No excl01

2. Known allergies to: Acetylsalicylic Acid (ASA), clopidogrel, ticlopidin, heparin or any other anticoagulant / antiplatelet required for PCI, contrast medium, sirolimus, or similar drugs; or the scaffold materials including Magnesium, Yttrium, Neodymium, Zirconium, Gadolinium, Dysprosium, Tantalum that cannot be adequately pre-medicated — ○ Yes ○ No excl02

3. Subjects on dialysis — ○ Yes ○ No excl03

4. Subject has clinical symtoms and/or electrocardiogram (ECG) changes consistent with acute ST elevation myocardial infarction (STEMI) within 72 hours prior to the index procedure. — ○ Yes ○ No excl04

Note: Hemodynamically stable non-STEMI (NSTEMI) subjects are eligible for study enrollment

5. Documented left ventricular ejection fraction (LVEF) ≤ 30% — ○ Yes ○ No excl05

6. Restenotic target lesion — ○ Yes ○ No excl06

7. Thrombus in target vessel — ○ Yes ○ No excl07

8. Target lesion is located in or supplied by a diseased (defined as vessel irregularity per angiogram and >20% stenosed lesion by visual estimation) arterial or venous bypass graft — ○ Yes ○ No excl08

9. Left main coronary artery disease — ○ Yes ○ No excl09

10. Ostial target lesion (within 5.0 mm of vessel origin) — ○ Yes ○ No excl10

11.Target lesion involves a side branch ≥2.0 mm in diameter — ○ Yes ○ No excl11

12. Target vessel (including side branches) has second lesion which requires treatment according to the investigator`s discretion	○ Yes ○ No excl12
13.Unsuccessful pre-dilatation, defined as minimal lumen diameter smaller than the respective crossing profile of Magmaris Scaffold and angiographic complications (e.g. distal embolization, side branch closure, extensive dissections), by visual estimation	○ Yes ○ No excl13
14. Planned surgery within 6 months of PCI unless dual antiplatelet therapy will be maintained	○ Yes ○ No excl14
15. Currently participating in another study and primary endpoint is not reached yet	○ Yes ○ No excl15

Form Name	Community
Inclusion/Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

Fertility Status

Fertility Status

Fertility status
- ○ Post-menopausal
- ○ Surgically sterile
- ○ Female of childbearing potential *

fertsts

If female of childbearing potential,
pregnancy test should be administered according to the local hospital procedure.

Date of pregnancy test

pregdtc

Pregnancy test result
- ○ Negative
- ○ Positive

pregres

excl01 - 1. Pregnant and / or breast feeding females or females who intend to become pregnant during the time of the registry - 102574
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl02 - 2. Known allergies to: Acetylsalicylic Acid (ASA), clopidogrel, ticlopidin, heparin or any other anticoagulant / antiplatelet required for PCI, contrast medium, sirolimus, or similar drugs; or the scaffold materials including Magnesium, Yttrium, Neodymium, Zirconium, Gadolinium, Dysprosium, Tantalum that cannot be adequately pre-medicated - 102575
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl03 - 3. Subjects on dialysis - 102576
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl04 - 4. Subject has clinical symtoms and/or electrocardiogram (ECG) changes consistent with acute ST elevation myocardial infarction (STEMI) within 72 hours prior to the index procedure. Note: Hemodynamically stable non-STEMI (NSTEMI) subjects are eligible for study enrollment - 102605
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl05 - 5. Documented left ventricular ejection fraction (LVEF) ≤ 30% - 102577
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl06 - 6. Restenotic target lesion - 102578
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl07 - 7. Thrombus in target vessel - 102579
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl08 - 8. Target lesion is located in or supplied by a diseased (defined as vessel irregularity per angiogram and >20% stenosed lesion by visual estimation) arterial or venous bypass graft - 102580
Choice Text | *Encoded Value*

Yes | 1
No | 0

excl09 - 9. Left main coronary artery disease - 102581
Choice Text | Encoded Value
Yes | 1
No | 0

excl10 - 10. Ostial target lesion (within 5.0 mm of vessel origin) - 102582
Choice Text | Encoded Value
Yes | 1
No | 0

excl11 - 11.Target lesion involves a side branch ≥2.0 mm in diameter - 102583
Choice Text | Encoded Value
Yes | 1
No | 0

excl12 - 12. Target vessel (including side branches) has second lesion which requires treatment according to the investigator`s discretion - 102584
Choice Text | Encoded Value
Yes | 1
No | 0

excl13 - 13.Unsuccessful pre-dilatation, defined as minimal lumen diameter smaller than the respective crossing profile of Magmaris Scaffold and angiographic complications (e.g. distal embolization, side branch closure, extensive dissections), by visual estimation - 102585
Choice Text | Encoded Value
Yes | 1
No | 0

excl14 - 14. Planned surgery within 6 months of PCI unless dual antiplatelet therapy will be maintained - 102586
Choice Text | Encoded Value
Yes | 1
No | 0

excl15 - 15. Currently participating in another study and primary endpoint is not reached yet - 102720
Choice Text | Encoded Value
Yes | 1
No | 0

fertsts - Fertility status - 102691
Choice Text | Encoded Value
Post-menopausal | 1
Surgically sterile | 2
Female of childbearing potential * | 3

incl01 - 1. Subject is ≥ 18 years of age - 101975
Choice Text | Encoded Value
Yes | 1
No | 0

incl02 - 2. Subject must be willing to sign a Patient Informed Consent (PIC) or Patient Data Release Form (PDRF) where applicable. - 101976
Choice Text | Encoded Value
Yes | 1
No | 0

incl03 - 3. Symptomatic coronary artery disease - 101977
Choice Text | Encoded Value
Yes | 1
No | 0

incl04 - 4. Subject with a maximum of two single de novo lesions in two different major epicardial vessels - 102565
Choice Text | Encoded Value
Yes | 1
No | 0

incl05 - 5. Target lesion length ≤ 21 mm by QCA or by visual estimation - 102566
Choice Text | Encoded Value
Yes | 1
No | 0

incl06 - 6. Target lesion stenosis by visual estimation: > 50% - < 100% and TIMI flow ≥1 - 102624
Choice Text | Encoded Value
Yes | 1
No | 0

incl07 - 7. Subject is eligible for Dual Anti Platelet Therapy (DAPT) - 102625
Choice Text | Encoded Value
Yes | 1
No | 0

pregres - Pregnancy test result - 102693
Choice Text | Encoded Value
Negative | 1
Positive | 2

Form Name	Community
Inclusion & Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and 3.0 enrolled subjects
[see 3.0-specific exclusion criteria indicated below]

Inclusion & Exclusion Criteria
Inclusion Criteria

Current visit is
visit

Inclusion/Exclusion Criteria

Inclusion Criteria

1. Subject is ≥ 18 years of age — Yes No incl01

2. Subject must be willing to sign a Patient Informed Consent (PIC) or Patient Data Release Form (PDRF) where applicable. — Yes No incl02

3. Symptomatic coronary artery disease — Yes No incl03

4. Subject with a maximum of two single de novo lesions in two different major epicardial vessels — Yes No incl04

5. Target lesion length ≤ 21 mm by QCA or by visual estimation — Yes No incl05

6. Target lesion stenosis by visual estimation: > 50% - < 100% and TIMI flow ≥1 — Yes No incl06

7. Subject is eligible for Dual Anti Platelet Therapy (DAPT) — Yes No incl07

8. Reference vessel diameter between 2.7 - 3.7 by visual estimation, depending on the scaffold size used — Yes No incl08_2

Form Name	Community
Inclusion & Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

Exclusion Criteria

Exclusion Criteria

1. Pregnant and / or breast feeding females or females who intend to become pregnant during the time of the registry

Yes
No
excl01

2. Known allergies to: Acetylsalicylic Acid (ASA), clopidogrel, ticlopidin, heparin or any other anticoagulant / antiplatelet required for PCI, contrast medium, sirolimus, or similar drugs; or the scaffold materials including Magnesium, Yttrium, Neodymium, Zirconium, Gadolinium, Dysprosium, Tantalum that cannot be adequately pre-medicated

Yes
No
excl02

3. Subjects on dialysis

Yes
No
excl03

4. Subject has clinical symtoms and/or electrocardiogram (ECG) changes consistent with acute ST elevation myocardial infarction (STEMI) within 72 hours prior to the index procedure.

Note: Hemodynamically stable non-STEMI (NSTEMI) subjects are eligible for study enrollment

Yes
No
excl04

5. Documented left ventricular ejection fraction (LVEF) ≤ 30%

Yes
No
excl05

5. Documented left ventricular ejection fraction (LVEF) < 30%

Yes
No
excl05_3

6. Restenotic target lesion

Yes
No
excl06

7. Thrombus in target vessel

Yes
No
excl07

8. Target lesion is located in or supplied by a diseased (defined as vessel irregularity per angiogram and >20% stenosed lesion by visual estimation) arterial or venous bypass graft

- Yes
- No

excl08

9. Left main coronary artery disease

- Yes
- No

excl09

10. Ostial target lesion (within 5.0 mm of vessel origin)

- Yes
- No

excl10

11.Target lesion involves a side branch ≥2.0 mm in diameter

- Yes
- No

excl11

12. Target vessel (including side branches) has second lesion which requires treatment according to the investigator`s discretion

- Yes
- No

excl12

13. Unsuccessful pre-dilatation, defined as residual stenosis rate more than 20 % and/or angiographic complications (e.g. distal embolization, side branch closure, extensive dissections), by visual estimation

- Yes
- No

excl13_2

13. Unsuccessful pre-dilatation, defined as residual stenosis rate more than 20% measured by QCA and / or angiographic complications (e.g. distal embolization, side branch closure, extensive dissections)

- Yes
- No

excl13_3

14. Planned surgery within 6 months of PCI unless dual antiplatelet therapy will be maintained

- Yes
- No

excl14

15. Currently participating in another study and primary endpoint is not reached yet

- Yes
- No

excl15

16. Planned interventional treatment of any non-target vessel within 30 days post procedure

- Yes
- No

excl16_2

16. Planned interventional treatment of any target or non-target vessel after index procedure

- Yes
- No

excl16_3

17. Planned intervention of the target vessel within 6-month after the index procedure

- Yes

No
excl17_2

Form Name	Community
Inclusion & Exclusion Criteria	CAVI C1503 BIOSOLVE-IV Version 9.0

Fertility Status

Fertility Status

Fertility status
- ○ Post-menopausal
- ○ Surgically sterile
- ○ Female of childbearing potential *

fertsts

For women of childbearing potential < 55 years of age, pregnancy testing must be performed within 72 hours prior to angiography according to the standard of care of a hospital.

Date of pregnancy test

pregdtc

Pregnancy test result
- ○ Negative
- ○ Positive

pregres

excl01 - 1. Pregnant and / or breast feeding females or females who intend to become pregnant during the time of the registry - 103218
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl02 - 2. Known allergies to: Acetylsalicylic Acid (ASA), clopidogrel, ticlopidin, heparin or any other anticoagulant / antiplatelet required for PCI, contrast medium, sirolimus, or similar drugs; or the scaffold materials including Magnesium, Yttrium, Neodymium, Zirconium, Gadolinium, Dysprosium, Tantalum that cannot be adequately pre-medicated - 103219
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl03 - 3. Subjects on dialysis - 103220
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl04 - 4. Subject has clinical symtoms and/or electrocardiogram (ECG) changes consistent with acute ST elevation myocardial infarction (STEMI) within 72 hours prior to the index procedure. Note: Hemodynamically stable non-STEMI (NSTEMI) subjects are eligible for study enrollment - 103221
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl05 - 5. Documented left ventricular ejection fraction (LVEF) ≤ 30% - 103222
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl05_3 - 5. Documented left ventricular ejection fraction (LVEF) < 30% - 103441
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl06 - 6. Restenotic target lesion - 103223
Choice Text | *Encoded Value*
Yes | 1
No | 0

excl07 - 7. Thrombus in target vessel - 103224
Choice Text | *Encoded Value*
Yes | 1

No | 0

excl08 - 8. Target lesion is located in or supplied by a diseased (defined as vessel irregularity per angiogram and >20% stenosed lesion by visual estimation) arterial or venous bypass graft - 103225
Choice Text | Encoded Value
Yes | 1
No | 0

excl09 - 9. Left main coronary artery disease - 103226
Choice Text | Encoded Value
Yes | 1
No | 0

excl10 - 10. Ostial target lesion (within 5.0 mm of vessel origin) - 103227
Choice Text | Encoded Value
Yes | 1
No | 0

excl11 - 11.Target lesion involves a side branch ≥2.0 mm in diameter - 103228
Choice Text | Encoded Value
Yes | 1
No | 0

excl12 - 12. Target vessel (including side branches) has second lesion which requires treatment according to the investigator`s discretion - 103229
Choice Text | Encoded Value
Yes | 1
No | 0

excl13_2 - 13. Unsuccessful pre-dilatation, defined as residual stenosis rate more than 20 % and/or angiographic complications (e.g. distal embolization, side branch closure, extensive dissections), by visual estimation - 103230
Choice Text | Encoded Value
Yes | 1
No | 0

excl13_3 - 13. Unsuccessful pre-dilatation, defined as residual stenosis rate more than 20% measured by QCA and / or angiographic complications (e.g. distal embolization, side branch closure, extensive dissections) - 103442
Choice Text | Encoded Value
Yes | 1
No | 0

excl14 - 14. Planned surgery within 6 months of PCI unless dual antiplatelet therapy will be maintained - 103231
Choice Text | Encoded Value
Yes | 1

No | 0

excl15 - 15. Currently participating in another study and primary endpoint is not reached yet - 103232
Choice Text | Encoded Value
Yes | 1
No | 0

excl16_2 - 16. Planned interventional treatment of any non-target vessel within 30 days post procedure - 103237
Choice Text | Encoded Value
Yes | 1
No | 0

excl16_3 - 16. Planned interventional treatment of any target or non-target vessel after index procedure - 103444
Choice Text | Encoded Value
Yes | 1
No | 0

excl17_2 - 17. Planned intervention of the target vessel within 6-month after the index procedure - 103238
Choice Text | Encoded Value
Yes | 1
No | 0

fertsts - Fertility status - 103233
Choice Text | Encoded Value
Post-menopausal | 1
Surgically sterile | 2
Female of childbearing potential * | 3

incl01 - 1. Subject is ≥ 18 years of age - 103211
Choice Text | Encoded Value
Yes | 1
No | 0

incl02 - 2. Subject must be willing to sign a Patient Informed Consent (PIC) or Patient Data Release Form (PDRF) where applicable. - 103212
Choice Text | Encoded Value
Yes | 1
No | 0

incl03 - 3. Symptomatic coronary artery disease - 103213
Choice Text | Encoded Value
Yes | 1
No | 0

incl04 - 4. Subject with a maximum of two single de novo lesions in two different major epicardial vessels - 103214

Choice Text | *Encoded Value*
Yes | 1
No | 0

incl05 - 5. Target lesion length ≤ 21 mm by QCA or by visual estimation - 103215
Choice Text | *Encoded Value*
Yes | 1
No | 0

incl06 - 6. Target lesion stenosis by visual estimation: > 50% - < 100% and TIMI flow ≥1 - 103216
Choice Text | *Encoded Value*
Yes | 1
No | 0

incl07 - 7. Subject is eligible for Dual Anti Platelet Therapy (DAPT) - 103217
Choice Text | *Encoded Value*
Yes | 1
No | 0

incl08_2 - 8. Reference vessel diameter between 2.7 - 3.7 by visual estimation, depending on the scaffold size used - 103236
Choice Text | *Encoded Value*
Yes | 1
No | 0

pregres - Pregnancy test result - 103235
Choice Text | *Encoded Value*
Negative | 1
Positive | 2

Form Name	Community
EQ5D Questionnaire	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

EQ5D Questionnaire

Current visit is _____
visit

EQ5D Questionnaire

EQ5D performed? ○ Yes ○ No
pqeq5yn

Mobility
- ○ I have no problems in walking about
- ○ I have some problems in walking about
- ○ I am confined to bed
- ○ Patient did not answer

pqeq5d1

Self-care
- ○ I have no problems with self-care
- ○ I have some problems washing or dressing myself
- ○ I am unable to wash or dress myself
- ○ Patient did not answer

pqeq5d2

Usual activities
- ○ I have no problems with performing my usual activities
- ○ I have some problems with performing my usual activities
- ○ I am unable to perform my usual activities
- ○ Patient did not answer

pqeq5d3

Pain/Discomfort
- ○ I have no pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have extreme pain or discomfort
- ○ Patient did not answer

pqeq5d4

Anxiety/Depression
- ○ I am not anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am extremely anxious or depressed
- ○ Patient did not answer

pqeq5d5

Visual Analogue Scale (VAS)

pqeq5d6

☐ Patient did not answer

pqeq5d6nd

pqeq5d1 - Mobility - 103241

Choice Text | *Encoded Value*

I have no problems in walking about | 1
I have some problems in walking about | 2
I am confined to bed | 3
Patient did not answer | 9

pqeq5d2 - Self-care - 103242

Choice Text | *Encoded Value*

I have no problems with self-care | 1
I have some problems washing or dressing myself | 2
I am unable to wash or dress myself | 3
Patient did not answer | 9

pqeq5d3 - Usual activities - 103243

Choice Text | *Encoded Value*

I have no problems with performing my usual activities | 1
I have some problems with performing my usual activities | 2
I am unable to perform my usual activities | 3
Patient did not answer | 9

pqeq5d4 - Pain/Discomfort - 103244

Choice Text | *Encoded Value*

I have no pain or discomfort | 1
I have moderate pain or discomfort | 2
I have extreme pain or discomfort | 3
Patient did not answer | 9

pqeq5d5 - Anxiety/Depression - 103245

Choice Text | *Encoded Value*

I am not anxious or depressed | 1
I am moderately anxious or depressed | 2
I am extremely anxious or depressed | 3
Patient did not answer | 9

pqeq5yn - EQ5D performed? - 103240

Choice Text | *Encoded Value*

Yes | 1
No | 0

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Medical History and Risk Factors
MI and TIA

Current visit is
visit

Medical History and Risk Factors

Event Date not exactly known:
If **Day** is unknown: enter **15** for **Day**
If **Day** and **Month** are unknown: enter **01JUL** for **Day** and **Month**

History of previous myocardial infarction ○ Yes ○ No
mhmi

Number of MIs
mhminum

Date of most recent MI
mhmidtc

Date of MI is
○ Exact
○ Day unknown
○ Month and Day unknown
mhmidtcsts

Type of most recent MI
○ STEMI
○ NSTEMI
○ Unknown
mhmics

History of stroke or TIA ○ Yes ○ No
mhtia

Date of most recent event
mhtiadtc

Date of event is
○ Exact
○ Day unknown
○ Month and Day unknown
mhtiadtcsts

Smoking habits

- ○ Never smoked
- ○ Ex-smoker
- ○ Current smoker

mhsmoke

Cigarette smoker within the last two years ?

○ Yes ○ No

mhsmoke2

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Risk Factors

Risk Factors

Renal disease
○ Yes ○ No
mhrenal

Under dialysis
○ Yes ○ No
mhdialysis

Hepatic disease
○ Yes ○ No
mhliver

Respiratory disease
○ Yes ○ No
mhresp

Hypertension
○ Yes ○ No
mhhypten

Hypercholesteremia
○ Yes ○ No
mhhyplip

Diabetes
○ No
○ Insulin dependent
○ Non-insulin dependent
mhdiabet

Congestive heart failure
○ Yes ○ No
mhchf

NYHA Class
○ I
○ II
○ III
○ IV
mhnyhacs

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Cancer

Cancer

Yes No
mhcancer

Breast
mhcancer1

Colon
mhcancer2

Kidney
mhcancer3

Leukemia
mhcancer4

Liver
mhcancer5

Lung
mhcancer6

Pancreas
mhcancer7

Prostate
mhcancer8

Skin
mhcancer9

Other
mhcancer99

Other cancer

mhcancert

Other relevant medical history/risk factor

Yes No
mhoth

Other relevant medical history/risk factors

See medical_history_other

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Previous Interventions Details

Previous coronary surgeries/interventions done ◯ Yes ◯ No
mhprvivn

Number of previous interventions
mhprvivnnum

See previous_intervention_details

mhcancer - Cancer - 102137
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhchf - Congestive heart failure - 102117
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhdiabet - Diabetes - 102116
Choice Text | *Encoded Value*
No | 0
Insulin dependent | 1
Non-insulin dependent | 2

mhdialysis - Under dialysis - 102111
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhhyplip - Hypercholesteremia - 102115
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhhypten - Hypertension - 102114
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhliver - Hepatic disease - 102112
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhmi - History of previous myocardial infarction - 102101
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhmics - Type of most recent MI - 102104
Choice Text | *Encoded Value*

STEMI | 1
NSTEMI | 2
Unknown | 100

mhmidtcsts - Date of MI is - 102108
Choice Text | *Encoded Value*
Exact | 1
Day unknown | 2
Month and Day unknown | 3

mhnyhacs - NYHA Class - 102118
Choice Text | *Encoded Value*
I | 1
II | 2
III | 3
IV | 4

mhoth - Other relevant medical history/risk factor - 102149
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhprvivn - Previous coronary surgeries/interventions done - 102135
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhrenal - Renal disease - 102110
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhresp - Respiratory disease - 102113
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhsmoke - Smoking habits - 102107
Choice Text | *Encoded Value*
Never smoked | 1
Ex-smoker | 2
Current smoker | 3

mhsmoke2 - Cigarette smoker within the last two years ? - 102723

Choice Text | *Encoded Value*
Yes | 1
No | 0

mhtia - History of stroke or TIA - 102105
Choice Text | *Encoded Value*
Yes | 1
No | 0

mhtiadtcsts - Date of event is - 102109
Choice Text | *Encoded Value*
Exact | 1
Day unknown | 2
Month and Day unknown | 3

Form Name	Community
Other Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Other Medical History and Risk Factors

Other Medical History and Risk Factors

Other relevant medical history/risk factor

mhotht

Current visit is

visit

Form Name	Community
Previous Coronary Intervention Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Medical History and Risk Factors	CAVI C1503 BIOSOLVE-IV Version 9.0

Previous Coronary Intervention Details

Current visit is
visit

Previous Coronary Intervention Details

Intervention Date not exactly known:
If **Day** is unknown: enter **15** for **Day**
If **Day** and **Month** are unknown: enter **01JUL** for **Day** and **Month**

For lesion location please refer to CASS map below

Previous intervention number (autopopulated by system)
piid

Date of previous intervention
pidtc

Date of previous intervention is
- Exact
- Day unknown
- Month and Day unknown
- Unknown

pidtcsts

Indication for intervention
- Myocardial infarction
- Angina pectoris
- Congestive heart failure
- Other

piterm

Other indication
pitermt

Type of intervention
- PTCA with uncoated balloon

- ○ PTCA with drug eluting balloon
- ○ Stenting with BMS
- ○ Stenting with DES
- ○ Stenting with other type of stent/scaffold
- ○ Thrombectomy
- ○ Thrombolysis
- ○ Atherectomy
- ○ Brachytherapy
- ○ CABG/Bypass
- ○ Other

pitype

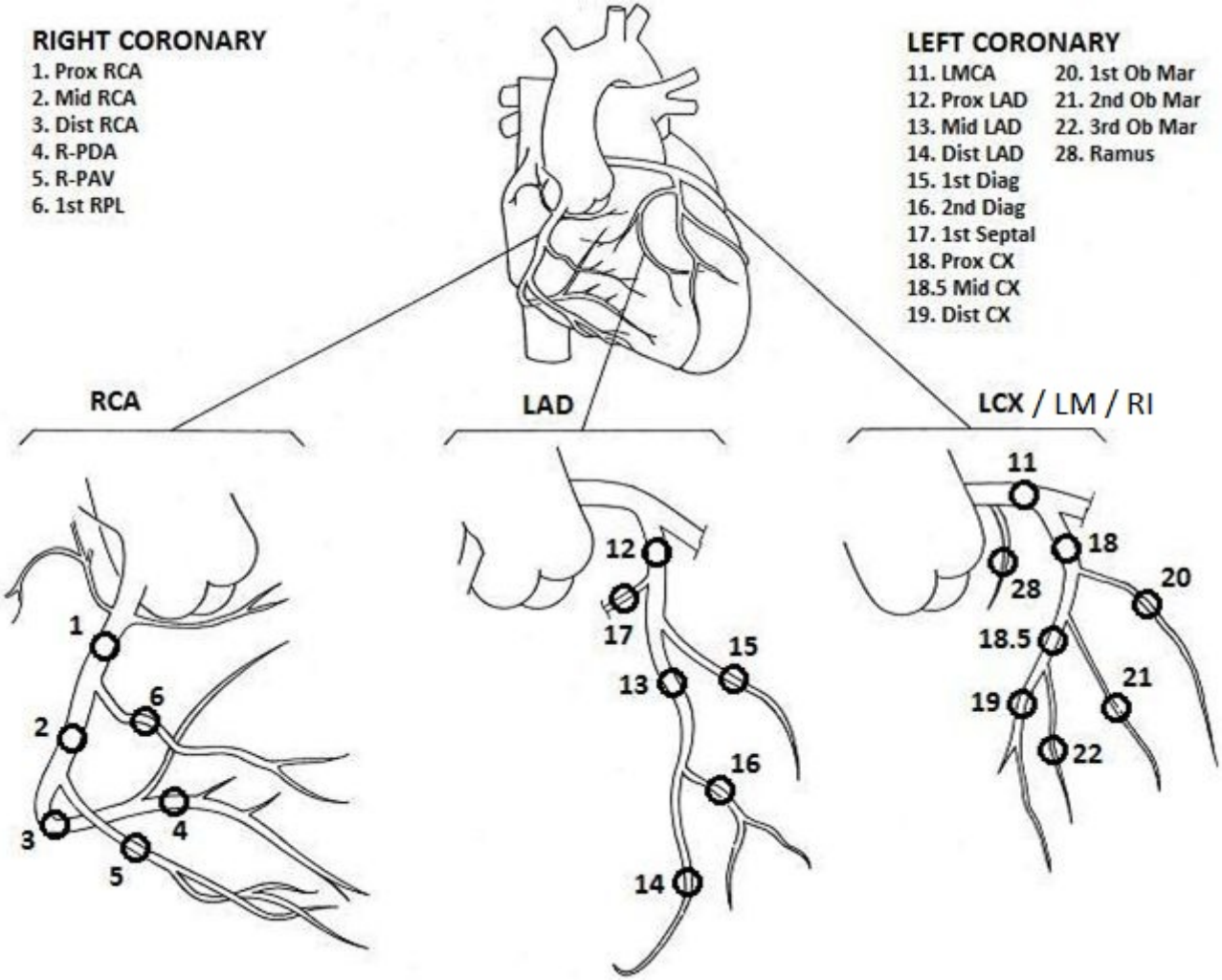
Other type of intervention

pitypet

Stent/scaffold name

pistnme

CASS map



pilesmap

Vessel [▼] (autopopulated by system)

pivessel

Lesion location [▼] (autopopulated by system)

pilesloc

☐ Location unknown

pileslocunk

pidtcsts - Date of previous intervention is - 102202

Choice Text | *Encoded Value*

Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 4

pilesloc - Lesion location - 102212

Choice Text | *Encoded Value*

Prox RCA | 1
Mid RCA | 2
Dist RCA | 3
R-PDA | 4
R-PAV | 5
1st RPL | 6
LMCA | 11
Prox LAD | 12
Mid LAD | 13
Dist LAD | 14
1st Diag | 15
2nd Diag | 16
1st Septal | 17
Prox CX | 18
Mid CX | 185
Dist CX | 19
1st Ob Mar | 20
2nd Ob Mar | 21
3rd Ob Mar | 22
Ramus | 28
Unknown | 100

pilesmap - CASS map - 102211

Choice Text | *Encoded Value*

Prox LAD
1st RPL
1st Septal
1st Diag
2d Diag
Dist LAD
Mid LAD
LMCA
Ramus
Prox CX
1st Ob Mar

Mid CX
Dist CX
2nd Ob Mar
3rd Ob Mar
Prox RCA
Mid RCA
Dist RCA
R-PAV
R-PDA

piterm - Indication for intervention - 102206

Choice Text | *Encoded Value*

Myocardial infarction | 1
Angina pectoris | 2
Congestive heart failure | 3
Other | 99

pitype - Type of intervention - 102208

Choice Text | *Encoded Value*

PTCA with uncoated balloon | 1
PTCA with drug eluting balloon | 2
Stenting with BMS | 3
Stenting with DES | 4
Stenting with other type of stent/scaffold | 5
Thrombectomy | 6
Thrombolysis | 7
Atherectomy | 8
Brachytherapy | 9
CABG/Bypass | 10
Other | 99

pivessel - Vessel - 102213

Choice Text | *Encoded Value*

RCA | 1
LAD | 2
LCX | 3
LM | 4
RI | 5
CABG | 6

Form Name	Community
Ischemic Status Pre-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Ischemic Status Pre-procedure

Current visit is

visit

Ischemic Status Pre-procedure

AMI

- Yes
- No

isami

If AMI, please specify:

- STEMI
- NSTEMI

isstemi

If no AMI, please specify ischemic status:

Ischemic status

- Stable angina
- Unstable angina
- Documented silent ischemia

iscs

Stable angina

CCS Class

- I
- II
- III
- IV

isccscs

Unstable angina

Braunwald classification

- IA
- IIA
- IIIA
- IB
- IIB
- IIIB-Tneg
- IIIB-Tpos
- IC
- IIC
- IIIC

isbrnwcs

Documented silent ischemia

- ECG at rest

isdsi1

- Exercise (bicycle or treadmill)

isdsi2

- Stress echo

isdsi3

- Stress MRI

isdsi4

- Pressure/Flow wire

isdsi5

- Other

isdsi99

Please specify "Other"

isotht

Left ventricular ejection fraction

Note: Documented LVEF < 30% is an exclusion criterion.

LVEF % [ ] %
efpct

OR LVEF class
- ○ Normal (>= 55%)
- ○ Mildly reduced (45-54%)
- ○ Moderately reduced (30-44%)
- ○ Severely reduced (< 30%)

efcs

Date of LVEF measurement [ ]
efdtc

efcs - LVEF class - 102161

Choice Text | *Encoded Value*

Normal (>= 55%) | 1
Mildly reduced (45-54%) | 2
Moderately reduced (30-44%) | 3
Severely reduced (< 30%) | 4

isami - AMI - 103172

Choice Text | *Encoded Value*

Yes | 1
No | 0

isbrnwcs - Braunwald classification - 102152

Choice Text | *Encoded Value*

IA | 10
IIA | 20
IIIA | 30
IB | 11
IIB | 21
IIIB-Tneg | 31
IIIB-Tpos | 32
IC | 12
IIC | 22
IIIC | 33

isccscs - CCS Class - 102151

Choice Text | *Encoded Value*

I | 1
II | 2
III | 3
IV | 4

iscs - Ischemic status - 102150

Choice Text | *Encoded Value*

Stable angina | 1
Unstable angina | 2
Documented silent ischemia | 3

isstemi - If AMI, please specify: - 103173

Choice Text | *Encoded Value*

STEMI | 1
NSTEMI | 2

Form Name	Community
Ischemic Status Pre-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

Ischemic Status Pre-procedure

Current visit is

visit

Ischemic Status Pre-procedure

AMI

- Yes
- No

isami

If AMI, please specify:

- STEMI
- NSTEMI

isstemi

If no AMI, please specify ischemic status:

Ischemic status

- Stable angina
- Unstable angina
- Documented silent ischemia

iscs

Stable angina

CCS Class

- I
- II
- III
- IV

isccscs

Unstable angina

Braunwald classification

- IA
- IIA
- IIIA
- IB
- IIB
- IIIB-Tneg
- IIIB-Tpos
- IC
- IIC
- IIIC

isbrnwcs

Documented silent ischemia

- ECG at rest

isdsi1

- Exercise (bicycle or treadmill)

isdsi2

- Stress echo

isdsi3

- Stress MRI

isdsi4

- Pressure/Flow wire

isdsi5

- Other

isdsi99

Please specify "Other"

isotht

Left ventricular ejection fraction

Pre-procedure LVEF measurements should be performed within 6 months.

LVEF measurements until hospital discharge are accepted for subjects that signed informed consent after the procedure.

Note: Documented LVEF < 30 % is an exclusion criterion.

LVEF % [ ] %
efpct

OR LVEF class
- Normal (>= 55%)
- Mildly reduced (45-54%)
- Moderately reduced (30-44%)
- Severely reduced (< 30%)

efcs

Date of LVEF measurement [ ]
efdtc

efcs - LVEF class - 103313

Choice Text | *Encoded Value*

Normal (>= 55%) | 1
Mildly reduced (45-54%) | 2
Moderately reduced (30-44%) | 3
Severely reduced (< 30%) | 4

isami - AMI - 103300

Choice Text | *Encoded Value*

Yes | 1
No | 0

isbrnwcs - Braunwald classification - 103304

Choice Text | *Encoded Value*

IA | 10
IIA | 20
IIIA | 30
IB | 11
IIB | 21
IIIB-Tneg | 31
IIIB-Tpos | 32
IC | 12
IIC | 22
IIIC | 33

isccscs - CCS Class - 103303

Choice Text | *Encoded Value*

I | 1
II | 2
III | 3
IV | 4

iscs - Ischemic status - 103302

Choice Text | *Encoded Value*

Stable angina | 1
Unstable angina | 2
Documented silent ischemia | 3

isstemi - If AMI, please specify: - 103301

Choice Text | *Encoded Value*

STEMI | 1
NSTEMI | 2

Form Name	Community
12-lead ECG	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

12-lead ECG

Current visit is

visit

12-Lead ECG

ECG performed ? ○ Yes ○ No

egdn

Date and time ECG done

Time (24hr): ▼ ▼ hr:min

egdtc

Clinically relevant findings ? ○ Yes ○ No

egcrf

Description of clinically relevant findings

egcrft

egcrf - Clinically relevant findings ? - 102165

Choice Text | *Encoded Value*

Yes | 1
No | 0

egdn - ECG performed ? - 102626

Choice Text | *Encoded Value*

Yes | 1
No | 0

Form Name	Community
12-lead ECG	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

12-lead ECG

Current visit is

visit

12-Lead ECG

A 12-lead electrocardiogram should be performed within 24 hours prior to procedure for NSTEMI and STEMI subjects and between 6 - 24 hours or at discharge, whichever comes first, after the index procedure according to the standard of care of a hospital.

ECG performed ? ○ Yes ○ No

egdn

Date and time ECG done

Time (24hr): ▼ ▼ hr:min

egdtc

Clinically relevant findings ? ○ Yes ○ No

egcrf

Description of clinically relevant findings

egcrft

egcrf - Clinically relevant findings ? - 103287

Choice Text | *Encoded Value*

Yes | 1
No | 0

egdn - ECG performed ? - 103285

Choice Text | *Encoded Value*

Yes | 1
No | 0

Form Name	Community
Cardiac Enzymes Pre-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Cardiac Enzymes Pre-procedure

Current visit is
visit

Cardiac Enzymes Pre-procedure

Pre-procedure cardiac enzyme tests should be performed according to the standard of care of a hospital.

Cardiac enzyme assessment done ? ○ Yes ○ No
lbceprf

Date and time of blood draw
Time (24hr): ▼ ▼ hr:min
lbcedtc

Parameter	Measurement done ?	Value	Unit	Other unit	Out of normal range ?	Clinically significant ?
CK	○ Yes ○ No lbckdn	lbckval	○ U/L ○ Other lbcku	lbckut	○ Yes ○ No lbckor	○ Yes ○ No lbcksg
CK-MB	○ Yes ○ No lbckmbdn	lbckmbval	○ U/L ○ µg/L ○ ng/mL ○ Other lbckmbu	lbckmbut	○ Yes ○ No lbckmbor	○ Yes ○ No lbckmbsg
Troponine (T or I)	○ Yes ○ No lbtropdn ○ -I ○ -T ○ -Ths	lbtropval	○ µg/L ○ ng/L ○ ng/mL ○ pg/mL ○ Other lbtropu	lbtroput	○ Yes ○ No lbtropor	○ Yes ○ No lbtropsg

lbtropit

lbceprf - Cardiac enzyme assessment done ? - 102167
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckdn - CK Done - 102169
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbdn - CK-MB Done - 102170
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbor - lbckmbor - 102184
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbsg - lbckmbsg - 102185
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbu - CK-MB Unit - 102177
Choice Text | *Encoded Value*
U/L | 1
µg/L | 31
ng/mL | 44
Other | 99

lbckor - lbckor - 102182
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcksg - lbcksg - 102183
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcku - CK Unit - 102176

Choice Text | *Encoded Value*
U/L | 1
Other | 99

lbtropdn - Troponine Done - 102171
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropit - xxxxx - 102172
Choice Text | *Encoded Value*
-I | 1
-T | 2
-Ths | 3

lbtropor - lbtropor - 102186
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropsg - lbtropsg - 102187
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropu - Troponine Unit - 102178
Choice Text | *Encoded Value*
µg/L | 31
ng/L | 41
ng/mL | 44
pg/mL | 54
Other | 99

Form Name	Community
Cardiac Enzymes Pre Procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

Cardiac Enzymes Pre Procedure

Current visit is
visit

Cardiac Enzymes Pre-procedure

Pre-procedure cardiac enzyme tests (preferably CK-MB and/or Troponin) should be performed within 24 hours according to the standard of care of a hospital.

Cardiac enzyme assessment done ? ○ Yes ○ No
lbceprf

Date and time of blood draw
Time (24hr): ▼ ▼ hr:min
lbcedtc

Parameter	Measurement done ?	Value	Unit	Other unit	Out of normal range ?	Clinically significant ?
CK	○ Yes ○ No lbckdn	lbckval	○ U/L ○ Other lbcku	lbckut	○ Yes ○ No lbckor	○ Yes ○ No lbcksg
CK-MB	○ Yes ○ No lbckmbdn	lbckmbval	○ U/L ○ µg/L ○ ng/mL ○ Other lbckmbu	lbckmbut	○ Yes ○ No lbckmbor	○ Yes ○ No lbckmbsg
Troponine (T or I)	○ Yes ○ No lbtropdn ○ -I ○ -T	lbtropval	○ µg/L ○ ng/L ○ ng/mL ○ pg/mL ○ Other lbtropu	lbtroput	○ Yes ○ No lbtropor	○ Yes ○ No lbtropsg

-Ths
lbtropit

lbceprf - Cardiac enzyme assessment done ? - 103263
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckdn - CK Done - 103265
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbdn - CK-MB Done - 103271
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbor - lbckmbor - 103275
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbsg - lbckmbsg - 103276
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbu - CK-MB Unit - 103273
Choice Text | *Encoded Value*
U/L | 1
µg/L | 31
ng/mL | 44
Other | 99

lbckor - lbckor - 103269
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcksg - lbcksg - 103270
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcku - CK Unit - 103267

Choice Text | *Encoded Value*
U/L | 1
Other | 99

lbtropdn - Troponine Done - 103277
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropit - xxxxx - 103283
Choice Text | *Encoded Value*
-I | 1
-T | 2
-Ths | 3

lbtropor - lbtropor - 103281
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropsg - lbtropsg - 103282
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbtropu - Troponine Unit - 103279
Choice Text | *Encoded Value*
µg/L | 31
ng/L | 41
ng/mL | 44
pg/mL | 54
Other | 99

Form Name	Community
Serum Creatinine Pre-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Serum Creatinine Pre-procedure

Current visit is
visit

Serum Creatinine Pre-procedure

Serum creatinine test should be performed according to the standard of care of a hospital.

Serum creatinine assessment done ? ○ Yes ○ No
lbscprf

Date and time of blood draw
Time (24hr): ▼ ▼ hr:min
lbscdtc

Serum creatinine Value
lbscval

Serum creatinine Unit
○ µmol/L
○ mg/dL
○ Other
lbscu

Serum creatinine Other unit
lbscut

Serum creatinine: Out of normal range ? ○ Yes ○ No
lbscor

Serum creatinine: Clinically significant ? ○ Yes ○ No
lbscsg

lbscor - Serum creatinine: Out of normal range ? - 102193

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscprf - Serum creatinine assessment done ? - 102188

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscsg - Serum creatinine: Clinically significant ? - 102194

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscu - Serum creatinine Unit - 102191

Choice Text | *Encoded Value*

µmol/L | 1
mg/dL | 22
Other | 99

Form Name	Community
Serum Creatinine Pre-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

Serum Creatinine Pre-procedure

Current visit is
visit

Serum Creatinine Pre-procedure

Pre-procedure serum creatinine test should be performed within 72 hours according to the standard of care of a hospital.

Serum creatinine assessment done ? ○ Yes ○ No
lbscprf

Date and time of blood draw
Time (24hr): ▼ ▼ hr:min
lbscdtc

Serum creatinine Value
lbscval

Serum creatinine Unit ○ µmol/L ○ mg/dL ○ Other
lbscu

Serum creatinine Other unit
lbscut

Serum creatinine: Out of normal range ? ○ Yes ○ No
lbscor

Serum creatinine: Clinically significant ? ○ Yes ○ No
lbscsg

lbscor - Serum creatinine: Out of normal range ? - 103295

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscprf - Serum creatinine assessment done ? - 103290

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscsg - Serum creatinine: Clinically significant ? - 103296

Choice Text | *Encoded Value*

Yes | 1
No | 0

lbscu - Serum creatinine Unit - 103293

Choice Text | *Encoded Value*

µmol/L | 1
mg/dL | 22
Other | 99

Form Name	Community
Procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Procedure

Current visit is
visit

Procedure

Date of procedure
procdtc

Date as integer
procdtc_intnum

Start time of procedure Time (24hr): hrs:min
pgsttmc

End time of procedure Time (24hr): hrs:min
pgentmc

Implanting physician
pgsurgeon

Vascular access site
- Femoral
- Brachial
- Radial

pgaccess

X-ray: Dose area product or effective dose
pgxrayval

X-ray dose unit
pgxrayu

X-ray: Dose-area product in cGy*cm2 cGy*cm2
pgxrayust

Name of contrast medium used
pgxcmnam

Amount of contrast medium used
pgxcmval

Contrast medium unit
pgxcmu

Contrast product in mL mL
pgxcmust

Target Vessel(s)

How many vessels are suitable for treatment with the Magmaris scaffold after diagnostic angiography ? (maximum is 2)

pgvesnum

Adverse Events

Did one or more AE, SAE, ADE or SADE event(s) occur during this procedure ?

Yes No

pganyae

Note: If any event occured during the procedure please complete an Adverse Event form for each event.

Device Deficiency

Has a device deficiency occurred prior or during the procedure ?

Yes No

pgdevdef

Note: If any device deficiency occurred prior or during the procedure please complete a Device Deficiency form

pgaccess - Vascular access site - 102311
Choice Text | Encoded Value
Femoral | 1
Brachial | 2
Radial | 3

pganyae - Did one or more AE, SAE, ADE or SADE event(s) occur during this procedure ? - 102316
Choice Text | Encoded Value
Yes | 1
No | 0

pgdevdef - Has a device deficiency occurred prior or during the procedure ? - 102688
Choice Text | Encoded Value
Yes | 1
No | 0

pgxcmu - Contrast medium unit - 102734
Choice Text | Encoded Value
mL | 1
cL | 2
cc | 3
mm3 | 4
cm3 | 5

pgxrayu - X-ray dose unit - 102733
Choice Text | Encoded Value
mSv | 1
µGy*m2 | 2
mGy*cm2 | 3
cGy*cm2 | 4
dGy*cm2 | 5
Gy*cm2 | 6

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Target Lesion Characterization
Lesion Location

Current visit is

visit

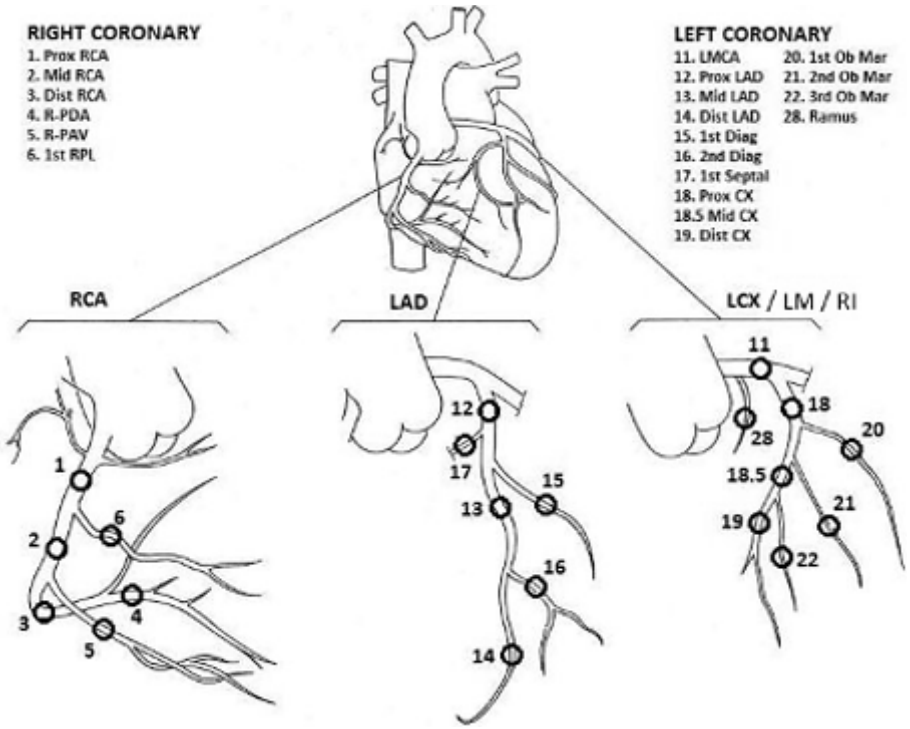
Target Lesion Characterization

Lesion ID (auto-populated by system)

lcid

Select the location by using the drop-down or by clicking on the map

CASS map



lccassmap

Lesion location [▼] (autopopulated by system)
lclesloc

Vessel [▼] (autopopulated by system)
lcvessel

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Lesion Characterization

Lesion Characterization

Pre-procedure TIMI flow distal to target lesion
○ Grade 0 ○ Grade 1 ○ Grade 2 ○ Grade 3
lctimipr

ACC / AHA lesion characterization
○ Type A ○ Type B1 ○ Type B2 ○ Type C
lcaccaha

Calcification
○ None ○ Mild ○ Moderate ○ Severe
lccalccs

Vessel angulation
○ None (< 45°) ○ Moderate (>= 45 - < 90°) ○ Severe (>= 90°)
lcvangul

Vessel tortuosity
○ Little ○ Moderate ○ Excessive
lctortsy

Bifurcation lesion ?
○ Yes ○ No
lcbifurc

Eccentricity
○ Concentric ○ Eccentric
lcecntry

Thrombus present ?
○ Yes ○ No
lcthrmbs

QCA or Visual estimation

Lesion length
[ ] mm
lclenv

Reference vessel diameter after Nitro/ ISDN i.c.
[ ] mm
lcrvdv

Stenosis pre-procedure
[ ] %
lcdsv

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Pre-dilatation

Pre-dilatation

Pre-dilatation performed ? ○ Yes ○ No
pdprdil

Number of pre-dilatation balloons used ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdprbnnum

Pre-dilatation Balloon Table

See tl_pre_dilatation_balloons

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Magmaris Scaffold Implantation

Magmaris Scaffold Implantation

Number of opened Magmaris scaffold packages ○ 0 ○ 1 ○ 2 ○ 3
ddstopennum

Magmaris Scaffold Table

See tl_study_scaffold

Number of Magmaris scaffolds that entered the guiding catheter ○ 0 ○ 1 ○ 2 ○ 3
ddstnum

Number of Magmaris scaffolds that were implanted ○ 0 ○ 1 ○ 2 ○ 3
ddstnumimpl

If 0 Magmaris scaffolds implanted:

Why was no Magmaris scaffold implanted ?
ddnotreatrnt

If > 1 Magmaris scaffolds used:

Reason for usage of multiple Magmaris scaffolds
○ 1st device could not be applied
○ Dissection
○ Other
ddgt1strn

Other reason for multiple Magmaris scaffold usage
ddgt1strnt

The Magmaris scaffolds were placed
○ End-to-end
○ Overlapping
○ Other
ddgt1stor

Other Magmaris scaffold placement
ddgt1stort

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Post-dilatation

Post-dilatation

Was any proBio coated stent (such as Orsiro or Pro-Kinetic Energy) implanted ? ○ Yes ○ No
pdpsst

Number of proBio (such as Orsiro or Pro-Kinetic Energy) implanted ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdpsstnum

Post-dilatation performed ? ○ Yes ○ No
pdpsdil

Number of post-dilatation balloons used ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdpsbnnum

Post-dilatation Balloon Table

See tl_post_dilatation_balloons

ddgt1stor - The Magmaris scaffolds were placed - 102339
Choice Text | *Encoded Value*
End-to-end | 1
Overlapping | 2
Other | 99

ddgt1strn - Reason for usage of multiple Magmaris scaffolds - 102337
Choice Text | *Encoded Value*
1st device could not be applied | 1
Dissection | 2
Other | 99

ddstnum - Number of Magmaris scaffolds that entered the guiding catheter - 102335
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

ddstnumimpl - Number of Magmaris scaffolds that were implanted - 102606
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

ddstopennum - Number of opened Magmaris scaffold packages - 102633
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

lcaccaha - ACC / AHA lesion characterization - 102323
Choice Text | *Encoded Value*
Type A | 1
Type B1 | 2
Type B2 | 3
Type C | 4

lcbifurc - Bifurcation lesion ? - 102327
Choice Text | *Encoded Value*
Yes | 1

No | 0

lccalccs - Calcification - 102324

Choice Text | Encoded Value

None | 0
Mild | 1
Moderate | 2
Severe | 3

lccassmap - CASS map - 102321

Choice Text | Encoded Value

1st RPL
Mid RCA
LMCA
Prox LAD
1st Septal
Mid LAD
1st Diag
2nd Diag
Dist LAD
R-PAV
R-PDA
Dist RCA
Prox RCA
Prox CX
Ramus
1st Ob Mar
Mid CX
Dist CX
3rd Ob Mar
2nd Ob Mar

lcecntry - Eccentricity - 102328

Choice Text | Encoded Value

Concentric | 1
Eccentric | 2

lclesloc - Lesion location - 102319

Choice Text | Encoded Value

Prox RCA | 1
Mid RCA | 2
Dist RCA | 3
R-PDA | 4
R-PAV | 5
1st RPL | 6

LMCA | 11
Prox LAD | 12
Mid LAD | 13
Dist LAD | 14
1st Diag | 15
2nd Diag | 16
1st Septal | 17
Prox CX | 18
Mid CX | 185
Dist CX | 19
1st Ob Mar | 20
2nd Ob Mar | 21
3rd Ob Mar | 22
Ramus | 28

lcthrmbs - Thrombus present ? - 102329
Choice Text | *Encoded Value*
Yes | 1
No | 0

lctimipr - Pre-procedure TIMI flow distal to target lesion - 102322
Choice Text | *Encoded Value*
Grade 0 | 0
Grade 1 | 1
Grade 2 | 2
Grade 3 | 3

lctortsy - Vessel tortuosity - 102326
Choice Text | *Encoded Value*
Little | 1
Moderate | 2
Excessive | 3

lcvangul - Vessel angulation - 102325
Choice Text | *Encoded Value*
None (< 45°) | 1
Moderate (>= 45 - < 90°) | 2
Severe (>= 90°) | 3

lcvessel - Vessel - 102320
Choice Text | *Encoded Value*
RCA | 1
LAD | 2
LCX | 3
LM | 4

RI | 5

pdprbnnum - Number of pre-dilatation balloons used - 102334
Choice Text | Encoded Value
1 | 1
2 | 2
3 | 3
4 | 4
5 | 5

pdprdil - Pre-dilatation performed ? - 102333
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsbnnum - Number of post-dilatation balloons used - 102342
Choice Text | Encoded Value
1
2
3
4
5

pdpsdil - Post-dilatation performed ? - 102341
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsst - Was any proBio coated stent (such as Orsiro or Pro-Kinetic Energy) implanted ? - 102634
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsstnum - Number of proBio (such as Orsiro or Pro-Kinetic Energy) implanted - 102635
Choice Text | Encoded Value
1
2
3
4
5

Form Name	Community
Target Lesion Pre-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Pre-dilatation Balloon Details

Target Lesion Pre-dilatation Balloon Details

Lesion ID [ ] (auto-populated by system)
lcid

Order of use [ ] (1, 2, 3, ...)
pdbnid

Balloon name [▼]
pdbname

Other balloon name [ ]
pdbnmoth

Balloon diameter [ ] mm
pdbndia

Balloon length [ ] mm
pdbnlen

Number of inflations [ ]
pdbnnoi

Maximum pressure applied [ ] atm
pdbnmax

Current visit is [ ]
visit

pdbname - Balloon name - 102744

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Target Lesion Post-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Post-dilatation Balloon Details

Target Lesion Post-dilatation Balloon Details

Lesion ID	(auto-populated by system) lcid
Order of use	(1, 2, 3, ...) pdbnid
Balloon name	▼ pdbname
Other balloon name	pdbnmoth
Balloon diameter	mm pdbndia
Balloon length	mm pdbnlen
Number of inflations	pdbnnoi
Maximum pressure applied	atm pdbnmax
Balloon diameter acc. to compliance chart at maximum pressure that was applied	mm pdbndiacc
Current visit is	

visit

pdbname - Balloon name - 102743

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Target Lesion Study Stent Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Study Stent Details
Magmaris Scaffold Details

Magmaris Scaffold Details

Lesion ID [ ] (auto-populated by system)
lcid

Order of use [ ] (1, 2, 3, ...)
ddstid

Lot number [ ]
ddstlot

Ref number [ ]
ddstref

Expiration date [ ] . [ ]
ddstexpdtc ddstexpdtc_intnum

Magmaris scaffold diameter [ ] mm
ddstdia

Magmaris scaffold length [ ] mm
ddstlen

Was the Magmaris scaffold implanted? ○ Yes ○ No
ddstimpl

Reason not implanted
○ Opened but not used
○ Contact with non-sterile surface

	○ Lesion could not be crossed ○ Malfunction ○ Other ddstnoimplrn
Other reason not implanted	ddstnoimplrnt
Maximum pressure applied	atm ddstmax
Inflation time	sec ddstitm

Device Success

Successful delivery of the scaffold to the target lesion site in the coronary artery	○ Yes ○ No ddstscfdeliver
Successful scaffold deployment	○ Yes ○ No ddstscfdeploy
Successful removal of the delivery system	○ Yes ○ No ddstscfremove
Safe removal of the device in case of deployment failure	○ Yes ○ No ○ NA ddstsafremove
Residual % stenosis	% ddsteres
Current visit is	visit

Form Name	Community
Target Lesion Study Stent Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Magmaris Scaffold Performance

Rate the Magmaris scaffold performance, using a scale from"Very poor" to "Very good" or "NA" for "Not Applicable", and compare the Magmaris scaffold performance to that of your current scaffold (BRS) and DES, using a scale from "Better" to "Worse"

Commercial BRS
ddstcompbrs

Commercial DES
ddstcompdes

Magmaris	Scaffold performance	vs. Commercial BRS	vs. Commercial DES
Guide wire friction	ddstgwfrictcs	ddstgwfrictbrs	ddstgwfrictdes
Trackability	ddsttrackcs	ddsttrackbrs	ddsttrackdes
Pushability	ddstpushcs	ddstpushbrs	ddstpushdes
Crossability	ddstcrosscs	ddstcrossbrs	ddstcrossdes
Scaffold conformability	ddstconfcs	ddstconfbrs	ddstconfdes
Inflation time	ddstitmcs	ddstitmbrs	ddstitmdes
Ease of removal after deployment	ddsteasecs	ddsteasebrs	ddsteasedes

Overall performance	ddstprfrmcs	ddstprfrmbrs	ddstprfrmdes

ddstconfbrs - X - 102652
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstconfcs - x - 102644
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstconfdes - X - 102660
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstcrossbrs - X - 102651
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstcrosscs - x - 102643
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstcrossdes - X - 102659
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddsteasebrs - X - 102654

Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddsteasecs - x - 102646
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddsteasedes - X - 102662
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstgwfrictbrs - X - 102648
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstgwfrictcs - x - 102640
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstgwfrictdes - X - 102656
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstimpl - Was the Magmaris scaffold implanted? - 102374
Choice Text | *Encoded Value*
Yes | 1

No | 0

ddstitmbrs - X - 102653
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstitmcs - x - 102645
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstitmdes - X - 102661
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstnoimplrn - Reason not implanted - 102636
Choice Text | *Encoded Value*
Opened but not used | 1
Contact with non-sterile surface | 2
Lesion could not be crossed | 3
Malfunction | 4
Other | 99

ddstprfrmbrs - X - 102655
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstprfrmcs - x - 102647
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5

NA | 98

ddstprfrmdes - X - 102663
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstpushbrs - X - 102650
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstpushcs - x - 102642
Choice Text | Encoded Value
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstpushdes - X - 102658
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstsafremove - Safe removal of the device in case of deployment failure - 102373
Choice Text | Encoded Value
Yes | 1
No | 0
NA | 101

ddstscfdeliver - Successful delivery of the scaffold to the target lesion site in the coronary artery - 102370
Choice Text | Encoded Value
Yes | 1
No | 0

ddstscfdeploy - Successful scaffold deployment - 102371
Choice Text | Encoded Value
Yes | 1
No | 0

ddstscfremove - Successful removal of the delivery system - 102372

Choice Text | *Encoded Value*

Yes | 1
No | 0

ddsttrackbrs - X - 102649

Choice Text | *Encoded Value*

Better | 1
Equal | 0
Worse | 2

ddsttrackcs - x - 102641

Choice Text | *Encoded Value*

Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddsttrackdes - X - 102657

Choice Text | *Encoded Value*

Better | 1
Equal | 0
Worse | 2

Form Name	Community
Procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

Procedure

Current visit is
visit

Interventional Procedure

Date of procedure
procdtc

Date as integer
procdtc_intnum

Start time of procedure Time (24hr): hrs:min
pgsttmc

End time of procedure Time (24hr): hrs:min
pgentmc

Implanting physician
pgsurgeon

Vascular access site
- Femoral
- Brachial
- Radial

pgaccess

X-ray: Dose area product or effective dose
pgxrayval

X-ray dose unit
pgxrayu

X-ray: Dose-area product in cGy*cm2 cGy*cm2
pgxrayust

Name of contrast medium used
pgxcmnam

Amount of contrast medium used
pgxcmval

Contrast medium unit
pgxcmu

Contrast product in mL mL
pgxcmust

Please send angiograms of index procedure to study management. Thanks!

Target Vessel(s)

How many vessels are suitable for treatment with the Magmaris scaffold after diagnostic angiography ? (maximum is 2)

pgvesnum

Target Lesion(s)

Have all lesions been treated during one procedure? ○ Yes ○ No

pglestr_2

Adverse Events

Did one or more AE, SAE, ADE or SADE event(s) occur during this procedure ? ○ Yes ○ No

pganyae

Note: If any event occured during the procedure please complete an Adverse Event form for each event.

Device Deficiency

Has a device deficiency occurred prior or during the procedure ? ○ Yes ○ No

pgdevdef

Note: If any device deficiency occurred prior or during the procedure please complete a Device Deficiency form

pgaccess - Vascular access site - 103321

Choice Text | *Encoded Value*

Femoral | 1
Brachial | 2
Radial | 3

pganyae - Did one or more AE, SAE, ADE or SADE event(s) occur during this procedure ? - 103330

Choice Text | *Encoded Value*

Yes | 1
No | 0

pgdevdef - Has a device deficiency occurred prior or during the procedure ? - 103331

Choice Text | *Encoded Value*

Yes | 1
No | 0

pglestr_2 - Have all lesions been treated during one procedure? - 103382

Choice Text | *Encoded Value*

Yes | 1
No | 0

pgxcmu - Contrast medium unit - 103327

Choice Text | *Encoded Value*

mL | 1
cL | 2
cc | 3
mm3 | 4
cm3 | 5

pgxrayu - X-ray dose unit - 103323

Choice Text | *Encoded Value*

mSv | 1
µGy*m2 | 2
mGy*cm2 | 3
cGy*cm2 | 4
dGy*cm2 | 5
Gy*cm2 | 6

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and 3.0 enrolled subjects
[see 3.0-specific fields indicated below]

Target Lesion Characterization
Lesion Location

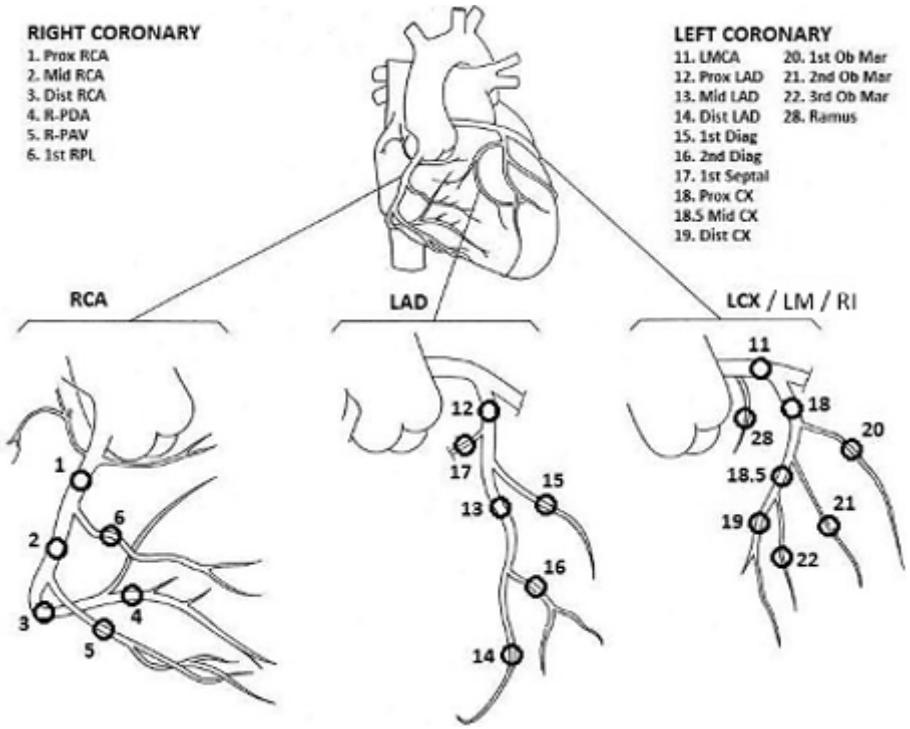
Current visit is
visit

Target Lesion Characterization

Lesion ID (auto-populated by system)
lcid

Select the location by using the drop-down or by clicking on the map

CASS map



lccassmap

Lesion location [▼] (autopopulated by system)
lclesloc

Vessel [▼] (autopopulated by system)
lcvessel

☐ CABG
lccabg

☐ Location unknown
lcleslocunk

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Lesion Characterization

Lesion Characterization

Pre-procedure TIMI flow distal to target lesion
○ Grade 0 ○ Grade 1 ○ Grade 2 ○ Grade 3
lctimipr

ACC / AHA lesion characterization
○ Type A ○ Type B1 ○ Type B2 ○ Type C
lcaccaha

Calcification
○ None ○ Mild ○ Moderate ○ Severe
lccalccs

Vessel angulation
○ None (< 45°) ○ Moderate (>= 45 - < 90°) ○ Severe (>= 90°)
lcvangul

Vessel tortuosity
○ Little ○ Moderate ○ Excessive
lctortsy

Bifurcation lesion ?
○ Yes ○ No
lcbifurc

Eccentricity
○ Concentric ○ Eccentric
lcecntry

Thrombus present ?
○ Yes ○ No
lcthrmbs

QCA, IVUS, OCT or Visual Estimation

Lesion length
[ ] mm
lclenv

Reference vessel diameter after Nitro/ ISDN i.c.
[ ] mm
lcrvdv

Stenosis pre-procedure
[ ] %
lcdsv

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Pre-dilatation

Pre-dilatation

Pre-dilatation with a non-compliant balloon with a 1:1 balloon-to-artery ratio is mandatory.
A 6F guiding catheter or larger should be used.
The balloon should expand fully.
The use of drug-coated balloons or rotational atherectomy devices is not allowed.

Pre-dilatation performed ? ○ Yes ○ No
pdprdil

Number of pre-dilatation balloons used ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdprbnnum

Residual % stenosis before Magmaris implantation [ ] %
pdrest

CIP 3.0 enrolled subjects
Residual stenosis measured by QCA ○ Yes ○ No
pdrestqca_3

Please send angiograms of index procedure to study management. Thanks!

Pre-dilatation Balloon Table

See tl_pre_dila_balloons

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Magmaris Scaffold Implantation

Magmaris Scaffold Implantation

Scaffold implantation and sizing should be performed in accordance with the instructions for use. Scaffold length should cover the target lesion from normal reference vessel diameter (RVD) proximal to normal RVD distal to assure full coverage of the lesion.

Only one scaffold should be used per lesion treatment.

Number of opened Magmaris scaffold packages ○ 0 ○ 1 ○ 2 ○ 3
ddstopennum

Magmaris Scaffold Table

See tl_magmaris

Number of Magmaris scaffolds that entered the guiding catheter ○ 0 ○ 1 ○ 2 ○ 3
ddstnum

Number of Magmaris scaffolds that were implanted ○ 0 ○ 1 ○ 2 ○ 3
ddstnumimpl

If 0 Magmaris scaffolds implanted:

Why was no Magmaris scaffold implanted ?
ddnotreatrnt

If > 1 Magmaris scaffolds used:

Reason for usage of multiple Magmaris scaffolds
○ 1st device could not be applied
○ Dissection
○ Other
ddgt1strn

Other reason for multiple Magmaris scaffold usage
ddgt1strnt

The Magmaris scaffolds were placed
○ End-to-end
○ Overlapping

	○ Other ddgt1stor
Other Magmaris scaffold placement	ddgt1stort

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Post-dilatation

Post-dilatation

Post-dilatation should be performed in accordance to the IFU of the balloon catheter.

Use of a non-compliant balloon at high pressure (> 16 atm) is recommended.

Please keep in mind that the Magmaris expansion limit is 0.6 mm beyond nominal scaffold size.

OTC may be helpful to check for malapposition.

Was any proBio coated stent (such as Orsiro or Pro-Kinetic Energy) implanted ? ○ Yes ○ No
pdpsst

Number of proBio (such as Orsiro or Pro-Kinetic Energy) implanted ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdpsstnum

Post-dilatation performed ? ○ Yes ○ No
pdpsdil

Number of post-dilatation balloons used ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
pdpsbnnum

Post-dilatation Balloon Table

See tl_post_dila_balloons

ddgt1stor - The Magmaris scaffolds were placed - 103356
Choice Text | *Encoded Value*
End-to-end | 1
Overlapping | 2
Other | 99

ddgt1strn - Reason for usage of multiple Magmaris scaffolds - 103354
Choice Text | *Encoded Value*
1st device could not be applied | 1
Dissection | 2
Other | 99

ddstnum - Number of Magmaris scaffolds that entered the guiding catheter - 103351
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

ddstnumimpl - Number of Magmaris scaffolds that were implanted - 103352
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

ddstopennum - Number of opened Magmaris scaffold packages - 103350
Choice Text | *Encoded Value*
0 | 0
1 | 1
2 | 2
3 | 3

lcaccaha - ACC / AHA lesion characterization - 103338
Choice Text | *Encoded Value*
Type A | 1
Type B1 | 2
Type B2 | 3
Type C | 4

lcbifurc - Bifurcation lesion ? - 103342
Choice Text | *Encoded Value*
Yes | 1

No | 0

lccalccs - Calcification - 103339

Choice Text | Encoded Value

None | 0
Mild | 1
Moderate | 2
Severe | 3

lccassmap - CASS map - 103334

Choice Text | Encoded Value

1st RPL
Mid RCA
LMCA
Prox LAD
1st Septal
Mid LAD
1st Diag
2nd Diag
Dist LAD
R-PAV
R-PDA
Dist RCA
Prox RCA
Prox CX
Ramus
1st Ob Mar
Mid CX
Dist CX
3rd Ob Mar
2nd Ob Mar

lcecntry - Eccentricity - 103343

Choice Text | Encoded Value

Concentric | 1
Eccentric | 2

lclesloc - Lesion location - 103335

Choice Text | Encoded Value

Prox RCA | 1
Mid RCA | 2
Dist RCA | 3
R-PDA | 4
R-PAV | 5
1st RPL | 6

LMCA | 11
Prox LAD | 12
Mid LAD | 13
Dist LAD | 14
1st Diag | 15
2nd Diag | 16
1st Septal | 17
Prox CX | 18
Mid CX | 185
Dist CX | 19
1st Ob Mar | 20
2nd Ob Mar | 21
3rd Ob Mar | 22
Ramus | 28

lcthrmbs - Thrombus present ? - 103344
Choice Text | *Encoded Value*
Yes | 1
No | 0

lctimipr - Pre-procedure TIMI flow distal to target lesion - 103337
Choice Text | *Encoded Value*
Grade 0 | 0
Grade 1 | 1
Grade 2 | 2
Grade 3 | 3

lctortsy - Vessel tortuosity - 103341
Choice Text | *Encoded Value*
Little | 1
Moderate | 2
Excessive | 3

lcvangul - Vessel angulation - 103340
Choice Text | *Encoded Value*
None (< 45°) | 1
Moderate (>= 45 - < 90°) | 2
Severe (>= 90°) | 3

lcvessel - Vessel - 103336
Choice Text | *Encoded Value*
RCA | 1
LAD | 2
LCX | 3
LM | 4

RI | 5

pdprbnnum - Number of pre-dilatation balloons used - 103349
Choice Text | Encoded Value
1 | 1
2 | 2
3 | 3
4 | 4
5 | 5

pdprdil - Pre-dilatation performed ? - 103348
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsbnnum - Number of post-dilatation balloons used - 103361
Choice Text | Encoded Value
1
2
3
4
5

pdpsdil - Post-dilatation performed ? - 103360
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsst - Was any proBio coated stent (such as Orsiro or Pro-Kinetic Energy) implanted ? - 103358
Choice Text | Encoded Value
Yes | 1
No | 0

pdpsstnum - Number of proBio (such as Orsiro or Pro-Kinetic Energy) implanted - 103359
Choice Text | Encoded Value
1
2
3
4
5

pdrestqca_3 - Residual stenosis measured by QCA - 103447
Choice Text | Encoded Value
Yes | 1

No | 0

Form Name	Community
Target Lesion Pre-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Pre-dilatation Balloon Details

Target Lesion Pre-dilatation Balloon Details

Lesion ID [ ] (auto-populated by system)
lcid

Order of use [ ] (1, 2, 3, ...)
pdbnid

Balloon name [▼]
pdbname

Other balloon name [ ]
pdbnmoth

Balloon diameter [ ] mm
pdbndia

Balloon length [ ] mm
pdbnlen

Number of inflations [ ]
pdbnnoi

Maximum pressure applied [ ] atm
pdbnmax

Current visit is [ ]
visit

pdbname - Balloon name - 103365

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Target Lesion Study Stent Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Study Stent Details
Magmaris Scaffold Details

Magmaris Scaffold Details

Lesion ID [ ] (auto-populated by system)
lcid

Order of use [ ] (1, 2, 3, ...)
ddstid

Lot number [ ]
ddstlot

Ref number [ ]
ddstref

Expiration date [ ] . [ ]
ddstexpdtc ddstexpdtc_intnum

Magmaris scaffold diameter [ ] mm
ddstdia

Magmaris scaffold length [ ] mm
ddstlen

Was the Magmaris scaffold implanted? ○ Yes ○ No
ddstimpl

Reason not implanted
○ Opened but not used
○ Contact with non-sterile surface

	○ Lesion could not be crossed ○ Malfunction ○ Other ddstnoimplrn
Other reason not implanted	ddstnoimplrnt
Maximum pressure applied	atm ddstmax
Inflation time	sec ddstitm

Device Success

Successful delivery of the scaffold to the target lesion site in the coronary artery	○ Yes ○ No ddstscfdeliver
Successful scaffold deployment	○ Yes ○ No ddstscfdeploy
Successful removal of the delivery system	○ Yes ○ No ddstscfremove
Safe removal of the device in case of deployment failure	○ Yes ○ No ○ NA ddstsafremove
Residual % stenosis after Magmaris implantation	% ddsteres
Current visit is	visit

Form Name	Community
Target Lesion Study Stent Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Magmaris Scaffold Performance

Rate the Magmaris scaffold performance, using a scale from"Very poor" to "Very good" or "NA" for "Not Applicable", and compare the Magmaris scaffold performance to that of your current scaffold (BRS) and DES, using a scale from "Better" to "Worse"

Commercial BRS
ddstcompbrs

Commercial DES
ddstcompdes

Magmaris	Scaffold performance	vs. Commercial BRS	vs. Commercial DES
Guide wire friction	ddstgwfrictcs	ddstgwfrictbrs	ddstgwfrictdes
Trackability	ddsttrackcs	ddsttrackbrs	ddsttrackdes
Pushability	ddstpushcs	ddstpushbrs	ddstpushdes
Crossability	ddstcrosscs	ddstcrossbrs	ddstcrossdes
Scaffold conformability	ddstconfcs	ddstconfbrs	ddstconfdes
Inflation time	ddstitmcs	ddstitmbrs	ddstitmdes
Ease of removal after deployment	ddsteasecs	ddsteasebrs	ddsteasedes

Overall performance	ddstprfrmcs	ddstprfrmbrs	ddstprfrmdes

ddstconfbrs - X - 103417
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstconfcs - x - 103416
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstconfdes - X - 103418
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstcrossbrs - X - 103414
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstcrosscs - x - 103413
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstcrossdes - X - 103415
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddsteasebrs - X - 103423

Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddsteasecs - x - 103422
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddsteasedes - X - 103424
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstgwfrictbrs - X - 103405
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstgwfrictcs - x - 103404
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstgwfrictdes - X - 103406
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstimpl - Was the Magmaris scaffold implanted? - 103391
Choice Text | *Encoded Value*
Yes | 1

No | 0

ddstitmbrs - X - 103420
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstitmcs - x - 103419
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstitmdes - X - 103421
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstnoimplrn - Reason not implanted - 103392
Choice Text | *Encoded Value*
Opened but not used | 1
Contact with non-sterile surface | 2
Lesion could not be crossed | 3
Malfunction | 4
Other | 99

ddstprfrmbrs - X - 103426
Choice Text | *Encoded Value*
Better | 1
Equal | 0
Worse | 2

ddstprfrmcs - x - 103425
Choice Text | *Encoded Value*
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5

NA | 98

ddstprfrmdes - X - 103427
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstpushbrs - X - 103411
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstpushcs - x - 103410
Choice Text | Encoded Value
Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddstpushdes - X - 103412
Choice Text | Encoded Value
Better | 1
Equal | 0
Worse | 2

ddstsafremove - Safe removal of the device in case of deployment failure - 103399
Choice Text | Encoded Value
Yes | 1
No | 0
NA | 101

ddstscfdeliver - Successful delivery of the scaffold to the target lesion site in the coronary artery - 103396
Choice Text | Encoded Value
Yes | 1
No | 0

ddstscfdeploy - Successful scaffold deployment - 103397
Choice Text | Encoded Value
Yes | 1
No | 0

ddstscfremove - Successful removal of the delivery system - 103398

Choice Text | *Encoded Value*

Yes | 1
No | 0

ddsttrackbrs - X - 103408

Choice Text | *Encoded Value*

Better | 1
Equal | 0
Worse | 2

ddsttrackcs - x - 103407

Choice Text | *Encoded Value*

Very good | 1
Good | 2
Acceptable | 3
Poor | 4
Very poor | 5
NA | 98

ddsttrackdes - X - 103409

Choice Text | *Encoded Value*

Better | 1
Equal | 0
Worse | 2

Form Name	Community
Target Lesion Post-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Target Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Target Lesion Post-dilatation Balloon Details

Target Lesion Post-dilatation Balloon Details

Lesion ID	(auto-populated by system) lcid
Order of use	(1, 2, 3, ...) pdbnid
Balloon name	▼ pdbname
Other balloon name	pdbnmoth
Balloon diameter	mm pdbndia
Balloon length	mm pdbnlen
Number of inflations	pdbnnoi
Maximum pressure applied	atm pdbnmax
Balloon diameter acc. to compliance chart at maximum pressure that was applied	mm pdbndiacc
Current visit is	

visit

pdbname - Balloon name - 103374

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Concomitant Medication Procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Concomitant Medication Procedure
ASA and Heparin

Current visit is _____
visit

Concomitant Medication Procedure

ASA		Dose	Unit	Other Unit
Patient on ASA prior to procedure (daily dose)	○ Yes ○ No cmasapp	cmasappd	○ mg ○ other cmasappu	cmasappdut
Patient received ASA loading dose	○ Yes ○ No cmasald	cmasaldd	○ mg ○ other cmasaldu	cmasaldut

Heparin		Dose	Unit	Other Unit
Heparin bolus injection prior to procedure	○ Yes ○ No cmheppp	cmhepppd	○ I.U. ○ other cmhepppu	cmheppput
Heparin during procedure	○ Yes ○ No cmhepdp	cmhepdpd	○ I.U. ○ other cmhepdpu	cmhepdput

Form Name	Community
Concomitant Medication Procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

Anti-Platelet

Anti-platelet Medication I		Dose	Unit	Other Unit
Anti-platelet medication I	cmplt			
Other Anti-platelet medication I	cmpltt			
Anti-platelet medication I prior to procedure (daily dose)	Yes No cmpltpp	cmpltppd	mg other cmpltppu	cmpltpput
Anti-platelet medication I loading dose	Yes No cmpltld	cmpltldd	mg other cmpltldu	cmpltldut

Anti-platelet Medication II		Dose	Unit	Other Unit	Duration
Anti-platelet medication II	cmplt2				
Anti-platelet medication II loading dose	Yes No cmplt2ld	cmplt2ldd	mg µg/min other cmplt2ldu	cmplt2ldut	Time (24hr): hrs:min cmplt2ldtmc
Anti-platelet medication II infusion	Yes No cmplt2dp	cmplt2dpd	mg/h ug/min other cmplt2dpu	cmplt2dput	Time (24hr): hrs:min cmplt2dptmc

cmasald - Patient received ASA loading dose - 102223
Choice Text | *Encoded Value*
Yes | 1
No | 0

cmasaldu - asaldu - 102225
Choice Text | *Encoded Value*
mg | 1
other | 99

cmasapp - Patient on ASA prior to procedure (daily dose) - 102219
Choice Text | *Encoded Value*
Yes | 1
No | 0

cmasappu - asappu - 102221
Choice Text | *Encoded Value*
mg | 1
other | 99

cmhepdp - Heparin during procedure - 102231
Choice Text | *Encoded Value*
Yes | 1
No | 0

cmhepdpu - cmhepdpu - 102233
Choice Text | *Encoded Value*
I.U. | 1
other | 99

cmheppp - Heparin bolus injection prior to procedure - 102227
Choice Text | *Encoded Value*
Yes | 1
No | 0

cmhepppu - cmhepppu - 102229
Choice Text | *Encoded Value*
I.U. | 1
other | 99

cmplt - Anti-platelet medication I - 102288
Choice Text | *Encoded Value*
Clopidogrel | 1
Prasugrel | 2
Ticagrelor | 3
Ticlopidine | 4
Other | 99
None | 0

cmplt2 - Anti-platelet medication II - 102298
Choice Text | Encoded Value
Bivalirudin | 1
Eptifibatid | 2
Abciximab | 3
Tirofiban | 4
None | 0

cmplt2dp - Anti-platelet medication II infusion - 102304
Choice Text | Encoded Value
Yes | 1
No | 0

cmplt2dpu - cmplt2dpu - 102306
Choice Text | Encoded Value
mg/h | 26
ug/min | 37
other | 99

cmplt2ld - Anti-platelet medication II loading dose - 102299
Choice Text | Encoded Value
Yes | 1
No | 0

cmplt2ldu - cmplt2ldu - 102301
Choice Text | Encoded Value
mg | 20
µg/min | 37
other | 99

cmpltld - Anti-platelet medication I loading dose - 102294
Choice Text | Encoded Value
Yes | 1
No | 0

cmpltldu - cmpltldu - 102296
Choice Text | Encoded Value
mg | 20
other | 99

cmpltpp - Anti-platelet medication I prior to procedure (daily dose) - 102290
Choice Text | Encoded Value
Yes | 1
No | 0

cmpltppu - cmpltppu - 102292
Choice Text | Encoded Value
mg | 20

other | 99

Form Name	Community
Hospital Discharge	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Hospital Discharge

Current visit is
visit

Hospital Discharge

Date of discharge
disdtc

Adverse Event

Did any AE, SAE, ADE or SADE event(s) occur since the procedure ? Yes No
disanyae

Note: If any event occured since the procedure, please complete an Adverse Event form for each new event.

Device Deficiency

Did any device deficiency occur between procedure and discharge ? Yes No
disdevdef

Note: If any device deficiency occurred after the procedure until discharge, please complete a Device Deficiency form.

Concomitant Medication

Medication Log reviewed ? Yes No
cmreview

cmreview - Medication Log reviewed ? - 102729

Choice Text | *Encoded Value*

Yes | 1
No | 0

disanyae - Did any AE, SAE, ADE or SADE event(s) occur since the procedure ? - 101863

Choice Text | *Encoded Value*

Yes | 1
No | 0

disdevdef - Did any device deficiency occur between procedure and discharge ? - 102689

Choice Text | *Encoded Value*

Yes | 1
No | 0

Form Name	Community
Cardiac Enzymes Post-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 enrolled subjects

Cardiac Enzymes Post-procedure

Current visit is

visit

Cardiac Enzymes Post-procedure

Post-procedure cardiac enzyme tests should be performed according to the standard of care of a hospital.

Cardiac enzyme assessment done ? ○ Yes ○ No

lbceprf

Post-procedure Cardiac Enzyme Assessments

See cardiac_enzymes_details

lbceprf - Cardiac enzyme assessment done ? - 102386

Choice Text	*Encoded Value*
Yes	1
No	0

Form Name	Community
Cardiac Enzymes Post-procedure Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Cardiac Enzymes Post-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

Cardiac Enzymes Post-procedure Details

Cardiac Enzymes Post-procedure Details

Date and time of blood draw

Time (24hr): ▼ ▼ hrs:min

lbcedtc

Parameter	Measurement done ?	Value	Unit	Other unit	Out of normal range ?	Clinically significant ?
CK	Yes No lbckdn	lbckval	U/L Other lbcku	lbckut	Yes No lbckor	Yes No lbcksg
CK-MB	Yes No lbckmbdn	lbckmbval	U/L µg/L ng/mL Other lbckmbu	lbckmbut	Yes No lbckmbor	Yes No lbckmbsg
Troponine (T or I)	Yes No lbtropdn -I -T -Ths lbtropit	lbtropval	µg/L ng/L ng/mL pg/mL Other lbtropu	lbtroput	Yes No lbtropor	Yes No lbtropsg

Current visit is

visit

lbckdn - CK Done - 102389
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbdn - CK-MB Done - 102395
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbor - lbckmbor - 102399
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbsg - lbckmbsg - 102400
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbu - CK-MB Unit - 102397
Choice Text | *Encoded Value*
U/L | 1
µg/L | 31
ng/mL | 44
Other | 99

lbckor - lbckor - 102393
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcksg - lbcksg - 102394
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcku - CK Unit - 102391
Choice Text | *Encoded Value*
U/L | 1
Other | 99

lbtropdn - Troponine Done - 102401
Choice Text | *Encoded Value*

Yes | 1
No | 0

lbtropit - lbtropit - 102407
Choice Text | Encoded Value
-I | 1
-T | 2
-Ths | 3

lbtropor - lbtropor - 102405
Choice Text | Encoded Value
Yes | 1
No | 0

lbtropsg - lbtropsg - 102406
Choice Text | Encoded Value
Yes | 1
No | 0

lbtropu - Troponine Unit - 102403
Choice Text | Encoded Value
µg/L | 31
ng/L | 41
ng/mL | 44
pg/mL | 54
Other | 99

Form Name	Community
Cardiac Enzymes Post-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 2.0 and CIP 3.0 enrolled subjects

Cardiac Enzymes Post-procedure

Current visit is

visit

Cardiac Enzymes Post-procedure

Post-procedure cardiac enzyme tests (preferably CK-MB and/or Troponin) should be performed between 6 - 24 hours or at discharge, whichever comes first, after the index procedure according to the standard of care of a hospital.

Cardiac enzyme assessment done ? Yes No

lbceprf

Post-procedure Cardiac Enzyme Assessments

See cardiac_enzymes_details

lbceprf - Cardiac enzyme assessment done ? - 103298

Choice Text	*Encoded Value*
Yes	1
No	0

Form Name	Community
Cardiac Enzymes Post-procedure Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Cardiac Enzymes Post-procedure	CAVI C1503 BIOSOLVE-IV Version 9.0

Cardiac Enzymes Post-procedure Details

Cardiac Enzymes Post-procedure Details

Date and time of blood draw

Time (24hr): ▼ ▼ hrs:min

lbcedtc

Parameter	Measurement done ?	Value	Unit	Other unit	Out of normal range ?	Clinically significant ?
CK	Yes No lbckdn	lbckval	U/L Other lbcku	lbckut	Yes No lbckor	Yes No lbcksg
CK-MB	Yes No lbckmbdn	lbckmbval	U/L µg/L ng/mL Other lbckmbu	lbckmbut	Yes No lbckmbor	Yes No lbckmbsg
Troponine (T or I)	Yes No lbtropdn -I -T -Ths lbtropit	lbtropval	µg/L ng/L ng/mL pg/mL Other lbtropu	lbtroput	Yes No lbtropor	Yes No lbtropsg

Current visit is

visit

lbckdn - CK Done - 102389
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbdn - CK-MB Done - 102395
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbor - lbckmbor - 102399
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbsg - lbckmbsg - 102400
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbckmbu - CK-MB Unit - 102397
Choice Text | *Encoded Value*
U/L | 1
µg/L | 31
ng/mL | 44
Other | 99

lbckor - lbckor - 102393
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcksg - lbcksg - 102394
Choice Text | *Encoded Value*
Yes | 1
No | 0

lbcku - CK Unit - 102391
Choice Text | *Encoded Value*
U/L | 1
Other | 99

lbtropdn - Troponine Done - 102401
Choice Text | *Encoded Value*

Yes | 1
No | 0

lbtropit - lbtropit - 102407
Choice Text | Encoded Value
-I | 1
-T | 2
-Ths | 3

lbtropor - lbtropor - 102405
Choice Text | Encoded Value
Yes | 1
No | 0

lbtropsg - lbtropsg - 102406
Choice Text | Encoded Value
Yes | 1
No | 0

lbtropu - Troponine Unit - 102403
Choice Text | Encoded Value
µg/L | 31
ng/L | 41
ng/mL | 44
pg/mL | 54
Other | 99

Form Name	Community
Ischemic Status Post-procedure/Follow-up	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Ischemic Status Post-procedure/Follow-up

Current visit is
visit

Ischemic Status Post-procedure/Follow-up

Ischemic status
- Without pathological findings
- Stable angina
- Unstable angina
- Documented silent ischemia

iscs

Stable angina

CCS Class
- I
- II
- III
- IV

isccscs

Unstable angina

Braunwald classification
- IA
- IIA
- IIIA
- IB
- IIB
- IIIB-Tneg
- IIIB-Tpos
- IC
- IIC
- IIIC

isbrnwcs

Documented silent ischemia

- ECG at rest
isdsi1
- Exercise (bicycle or treadmill)
isdsi2
- Stress echo
isdsi3
- Stress MRI
isdsi4
- Pressure/Flow wire
isdsi5
- Other
isdsi99

Please specify "Other"
isotht

isbrnwcs - Braunwald classification - 102410

Choice Text | Encoded Value

IA | 10
IIA | 20
IIIA | 30
IB | 11
IIB | 21
IIIB-Tneg | 31
IIIB-Tpos | 32
IC | 12
IIC | 22
IIIC | 33

isccscs - CCS Class - 102409

Choice Text | Encoded Value

I | 1
II | 2
III | 3
IV | 4

iscs - Ischemic status - 102408

Choice Text | Encoded Value

Without pathological findings | 0
Stable angina | 1
Unstable angina | 2
Documented silent ischemia | 3

Form Name	Community
Follow-up	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Follow-up

Current visit is
visit

Follow-up

Unscheduled follow-up ID (auto-populated for unscheduled follow-ups)
fgid

Follow-up visit performed ?
Yes No
fupdn

If not performed, reason follow-up not performed
Early termination
Missed visit
fupndrn

If performed:

Type of contact
Inpatient
Outpatient
Telephone
Other communication method
fgtype

Visit Status
1 Performed - Inpatient
2 Performed - Outpatient
3 Performed - Telephone
4 Performed - Other communication method
5 Not Performed - Early termination
6 Not Performed - Missed visit
svstatus

If "Other communication method", please specify:
fgcntacttypet

Date of follow-up
fupdtc

Date in days
svdatnum

Number of days since procedure
svprcdur

Did any AE, SAE, ADE or SADE occur since last follow-up or during this follow-up ?
Yes No
fganyae

Note: If any new event occured, please complete an Adverse Event form for each new event.

Has a device deficiency occurred since the last follow-up ?	○ Yes ○ No fgdevdef **Note: If any device deficiency occurred since the follow-up, please complete a Device Deficiency form**
Angiography done during or following this visit ?	○ Yes ○ No fgangiodn **Note: If angiography has been done during or following this visit, please complete a Repeat Angiography / Repeat Intervention form**
Medication Log reviewed ?	○ Yes ○ No fgcmdn
Unscheduled visits: Additional assessments	[ ] txtadditassess
Ischemic status assessed ?	○ Yes ○ No fgisdn

fgangiodn - Angiography done during or following this visit ? - 101922
Choice Text | Encoded Value
Yes | 1
No | 0

fganyae - Did any AE, SAE, ADE or SADE occur since last follow-up or during this follow-up ? - 101916
Choice Text | Encoded Value
Yes | 1
No | 0

fgcmdn - Medication Log reviewed ? - 102422
Choice Text | Encoded Value
Yes | 1
No | 0

fgdevdef - Has a device deficiency occurred since the last follow-up ? - 102690
Choice Text | Encoded Value
Yes | 1
No | 0

fgisdn - Ischemic status assessed ? - 102421
Choice Text | Encoded Value
Yes | 1
No | 0

fgtype - Type of contact - 101920
Choice Text | Encoded Value
Inpatient | 1
Outpatient | 2
Telephone | 6
Other communication method | 99

fupdn - Follow-up visit performed ? - 102665
Choice Text | Encoded Value
Yes | 1
No | 0

fupndrn - If not performed, reason follow-up not performed If performed: - 101924
Choice Text | Encoded Value
Early termination | 4
Missed visit | 5

svstatus - Visit Status - 102666
Choice Text | Encoded Value
1 Performed - Inpatient | 1
2 Performed - Outpatient | 2
3 Performed - Telephone | 6
4 Performed - Other communication method | 9
5 Not Performed - Early termination | 4
6 Not Performed - Missed visit | 5

Form Name	Community
Study Termination	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Study Termination
Study Termination

Current visit is
visit

Study Termination

* = field must be completed

Study termination was
- Regular
- Early

stwas

Reason for early termination
- Patient withdrew consent
- Patient lost to follow-up
- Patient died
- Other

strn

Date of early termination for definition see page "Completion guideline"
stdtc

Comment (optional)
stcomment

If the following question is answered "Yes" forms cannot be added or modified.
If additional data entry is required, please set the answer to this question to No.

Is data entry for this patient complete? * Yes No
stcomplete

Form Name	Community
Study Termination	CAVI C1503 BIOSOLVE-IV Version 9.0

Completion Guideline

Definition of date of early termination

for **early** study termination due to:

Patient withdrawal: date when the patient informed the site of study withdrawal

Lost to follow-up: the last date when the site tried to contact the patient

Subject will not be considered as "Lost to follow-up" until the end of the study.
For each scheduled follow-up the site has to try to contact the subject.

Other: date other reason occured

stcomplete - Is data entry for this patient complete? * - 101874

Choice Text | *Encoded Value*

Yes | 1
No | 2

strn - Reason for early termination - 101860

Choice Text | *Encoded Value*

Patient withdrew consent | 1
Patient lost to follow-up | 2
Patient died | 3
Other | 99

stwas - Study termination was - 101859

Choice Text | *Encoded Value*

Regular | 1
Early | 2

Form Name	Community
Repeat Angiography/Intervention	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Repeat Angiography/Intervention

Current visit is

visit

Repeat Angiography/Intervention

Repeat angio ID (auto-populated by system)
raid

Reason for angiography
- Clinically indicated
- Staged procedure
- new in V9.0 Standard of care

rarn

Date of angiography
radtc

Is this repeat angiography related to an adverse event ? Yes No
rarelae

Number of related adverse event
aeid

Did any AE, SAE, ADE or SADE occur during or after re-angiography and/or re-intervention ? Yes No
raanyae

Note: If any new event occured, please complete an Adverse Event form for each new event.

Percutaneous revascularization done after the diagnostic procedure ? Yes No
rapcrdn

Number of lesions treated
rapcrnum

Note: Please send the CD to: BIOTRONIK AG, Department Clinical Affairs, Ackerstrasse 6, 8180 Buelach, Switzerland

raanyae - Did any AE, SAE, ADE or SADE occur during or after re-angiography and/or re-intervention ? - 102447

Choice Text | *Encoded Value*

Yes | 1
No | 0

rapcrdn - Percutaneous revascularization done after the diagnostic procedure ? - 102449

Choice Text | *Encoded Value*

Yes | 1
No | 0

rarelae - Is this repeat angiography related to an adverse event ? - 102445

Choice Text | *Encoded Value*

Yes | 1
No | 0

rarn - Reason for angiography - 102443

Choice Text | *Encoded Value*

Clinically indicated | 2
Staged procedure | 3
Standard of care | 1

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Repeat Angiography Lesion Characterization
Lesion Location

Current visit is
visit

Repeat Angiography/Intervention Lesion Characterization

Repeat angio ID (auto-populated by system)
raid

Revascularization ID (auto-populated by system)
riid

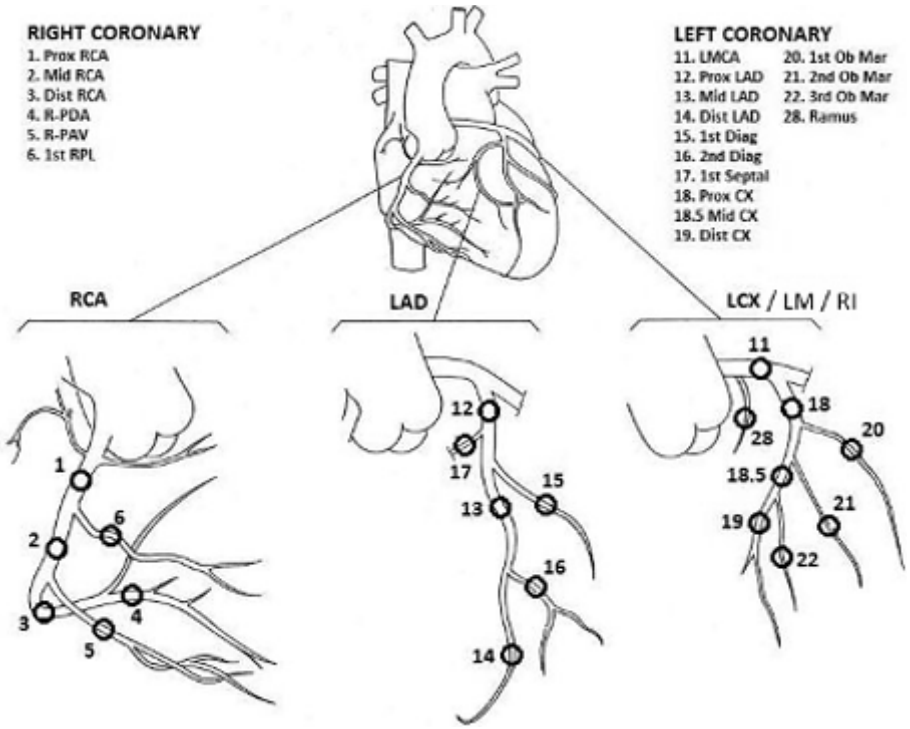
Type of revascularization
- TLR
- TVR
- non-TVR

ripcrloc

Target lesion ID
lcid

Please select a location from the drop-down or by clicking on the map

CASS map



ricassmap

Lesion location [ ] (autopopulated by system)
rilesloc

Vessel [ ] (autopopulated by system)
rivessel

Revascularization clinically driven ? ○ Yes ○ No
ripcrcld

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Lesion Characterization

Kind of re-intervention ▼
riinvtype

Other kind of re-intervention
riinvtypet

Pre-intervention TIMI flow distal to lesion
- Grade 0
- Grade 1
- Grade 2
- Grade 3

riprtimi

Lesion type
- de novo
- In-stent
- In-scaffold

rilstype

Bifurcation lesion ? Yes No
ribifurc

Thrombus present ? Yes No
rithrmbs

QCA or visual estimation

Lesion length mm
rilenv

Reference vessel diameter mm
rirvdv

Stenosis pre-procedure %
ridsv

Residual stenosis post-procedure %
rirdsv

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

PTCA only or Pre-dilatation

Pre-dilatation (or PTCA only) performed ? ◯ Yes ◯ No
riprdil

Number of PTCA/pre-dilatation balloons used
riprbnnum

PTCA/Pre-dilatation Balloon Table

See ra_pre_dilatation_balloons

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Stenting/DEB

Number of devices used to treat this lesion

ristnum

Devices Used Table

See ra_stent

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Post-dilatation

Post-dilatation performed ? ◯ Yes ◯ No
ripsdil

Number of post-dilatation balloons used
ripsbnnum

Post-dilatation Balloon Table

See ra_post_dilatation_balloons

ribifurc - Bifurcation lesion ? - 102465

Choice Text | *Encoded Value*

Yes | 1
No | 0

ricassmap - CASS map - 102745

Choice Text | *Encoded Value*

1st RPL
Mid RCA
LMCA
Prox LAD
1st Septal
Mid LAD
1st Diag
2nd Diag
Dist LAD
R-PAV
R-PDA
Dist RCA
Prox RCA
Prox CX
Ramus
1st Ob Mar
Mid CX
Dist CX
3rd Ob Mar
2nd Ob Mar

riinvtype - Kind of re-intervention - 102461

Choice Text | *Encoded Value*

PTCA with uncoated balloon | 1
PTCA with drug eluting balloon | 2
Stenting with BMS | 3
Stenting with DES | 4
Stenting with other kind of stent/scaffold | 5
Thrombectomy | 6
Trombolysis | 7
Atherectomy | 8
Brachytherapy | 9
CABG/Bypass | 10
Other procedure | 99

rilesloc - Lesion location - 102668

Choice Text | *Encoded Value*

Prox RCA | 1
Mid RCA | 2
Dist RCA | 3
R-PDA | 4
R-PAV | 5
1st RPL | 6
LMCA | 11
Prox LAD | 12
Mid LAD | 13
Dist LAD | 14
1st Diag | 15
2nd Diag | 16
1st Septal | 17
Prox CX | 18
Mid CX | 185
Dist CX | 19
1st Ob Mar | 20
2nd Ob Mar | 21
3rd Ob Mar | 22
Ramus | 28
Unknown | 100

rilstype - Lesion type - 102464
Choice Text | *Encoded Value*
de novo | 1
In-stent | 2
In-scaffold | 3

ripcrcld - Revascularization clinically driven ? - 102460
Choice Text | *Encoded Value*
Yes | 1
No | 0

ripcrloc - Type of revascularization - 102459
Choice Text | *Encoded Value*
TLR | 1
TVR | 2
non-TVR | 3

riprdil - Pre-dilatation (or PTCA only) performed ? - 102472
Choice Text | *Encoded Value*
Yes | 1
No | 0

riprtimi - Pre-intervention TIMI flow distal to lesion - 102463

Choice Text | *Encoded Value*
Grade 0 | 0
Grade 1 | 1
Grade 2 | 2
Grade 3 | 3

ripsdil - Post-dilatation performed ? - 102474
Choice Text | *Encoded Value*
Yes | 1
No | 0

rithrmbs - Thrombus present ? - 102466
Choice Text | *Encoded Value*
Yes | 1
No | 0

rivessel - Vessel - 102667
Choice Text | *Encoded Value*
RCA | 1
LAD | 2
LCX | 3
LM | 4
RI | 5
CABG | 6

Form Name	Community
Repeat Angiography Pre-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Repeat Angiography Pre-dilatation Balloon Details

Repeat Angiography/Intervention - PTCA / Pre-dilatation Balloon Details

Repeat angio ID [ ] (auto-populated by system)
raid

Revascularization ID [ ] (auto-populated by system)
riid

Order of use [ ] (1, 2, 3, ...)
ribnid

Balloon name [ ]
pdbname

Other balloon name [ ]
pdbnmoth

Balloon diameter [ ] mm
pdbndia

Balloon length [ ] mm
pdbnlen

Number of inflations [ ]
pdbnnoi

Maximum pressure applied [ ] atm
pdbnmax

Current visit is [ ]

visit

pdbname - Balloon name - 102746

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Repeat Angiography Stent Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Repeat Angiography Stent Details

Repeat Angiography/Intervention - Device Details

Repeat angio ID [ ] (auto-populated by system)
raid

Revascularization ID [ ] (auto-populated by system)
riid

Order of use [ ] (1, 2, 3, ...)
ristid

Device type
- DEB
- BMS
- DES
- Scaffold

risttype

Device name [ ]
ristnme

Device diameter [ ] mm
ristdia

Device length [ ] mm
ristlen

Number of inflations [ ]
ristnoi

Maximum pressure applied [ ] atm

ristmax

Current visit is

visit

risttype - Device type - 102510

Choice Text | Encoded Value

DEB | 2
BMS | 3
DES | 4
Scaffold | 5

Form Name	Community
Repeat Angiography Post-dilatation Balloon Details	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Repeat Angiography Lesion Characterization	CAVI C1503 BIOSOLVE-IV Version 9.0

Repeat Angiography Post-dilatation Balloon Details

Repeat Angiography/Intervention - Post-dilatation Balloon Details

Repeat angio ID [ ] (auto-populated by system)
raid

Revascularization ID [ ] (auto-populated by system)
riid

Order of use [ ] (1, 2, 3, ...)
ribnid

Balloon name [ ]
pdbname

Other balloon name [ ]
pdbnmoth

Balloon diameter [ ] mm
pdbndia

Balloon length [ ] mm
pdbnlen

Number of inflations [ ]
pdbnnoi

Maximum pressure applied [ ] atm
pdbnmax

Balloon diameter acc. to compliance chart at maximum pressure that was applied [ ] mm

pdbndiacc

Current visit is

visit

pdbname - Balloon name - 102747

Choice Text | Encoded Value

AACHEN RESONANCE / ELUTAX | 146
ABBOTT VASCULAR DEVICES / MINI TREK | 201
ABBOTT VASCULAR DEVICES / NC MERCURY | 106
ABBOTT VASCULAR DEVICES / NC TREK | 107
ABBOTT VASCULAR DEVICES / TREK | 108
ABBOTT VASCULAR DEVICES / VOYAGER | 109
ABBOTT VASCULAR DEVICES / VOYAGER NC | 110
ALVIMEDICA / INVADER | 111
AMG / ISTAR | 112
ATRIUM / HYPERLITE RX | 113
B. BRAUN / SEQUENT PLEASE | 147
BALTON / FRYDERYK | 114
BALTON / RIVER | 115
BBRAUN / SEQUENT II | 116
BIOTRONIK / ANGIOSCULPT | 104
BIOTRONIK / PANTERA | 101
BIOTRONIK / PANTERA ELECT | 102
BIOTRONIK / PANTERA LEO | 103
BIOTRONIK / PANTERA LUX | 145
BIOTRONIK / PANTERA PRO | 105
BLUE MEDICAL / FORCE NC | 117
BOSTON SCIENTIC / APEX | 118
BOSTON SCIENTIC / EMERGE | 121
BOSTON SCIENTIC / MAVERICK | 119
BOSTON SCIENTIC / NC QUANTUM APEX | 120
BOSTON SCIENTIC / QUANTUM MAVERICK | 122
BOSTON SCIENTIFIC / AGENT | 2601
BOSTON SCIENTIFIC / FLEXTOME | 123
CID / FLUYODO | 124
CORDIS / DURASTAR | 125
CORDIS / EMPIRA | 1003
CORDIS / EMPIRA NC | 1004
CORDIS / FIRE STAR | 126
EUROCOR / AMADEUS SUPERCROSS | 127
EUROCOR / DIOR | 148
IHT / FAIRWAY | 128
INVATEC / FALCON BRAVO | 129
INVATEC / FALCON FORTE | 130
INVATEC MEDTRONIC / IN.PACT FALCON | 149
MEDTRONIC / EUPHORA | 1305
MEDTRONIC / NC EUPHORA | 1306
MEDTRONIC / SPRINTER | 133
MEDTRONIC / SPRINTER LEGEND | 131

MEDTRONIC / SPRINTER NC | 132
MEDTRONIC / STORMER NC | 134
MERIL LIFE SCIENCES / XPEDIENT | 135
MINVASYS / DANUBIO | 150
NATEC MEDICAL LTD / FILAO NC | 136
NATEC MEDICAL LTD / FILAO RX | 137
ORBUS NEICH / SAFECUT | 139
ORBUS NEICH / SAPHIRE | 138
OTHER | 9999
SIS Medical / BEO NC | 140
TERUMO / ACCUFORCE | 1804
TERUMO / HIRYU | 141
TERUMO / RYUJIN PLUS | 142
TERUMO / TAZUNA | 143

Form Name	Community
Medication Log	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Medication Log

Current visit is

visit

Medication Log

This form must be reviewed at every follow-up visit and updated, if required.

Anti-platelet medication:
- Document changes in the combination of drugs.
- Start date is the first day the patient takes the drug/combination of drugs specified.
- Stop date is the last day the patient takes the drug/combination of drugs specified.
- If medication is changed or stopped briefly and restarted, a new row has to be added to designate the change.

See medication_dapt

Statins

See medication_statins

Form Name	Community
Medication DAPT	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Medication Log	CAVI C1503 BIOSOLVE-IV Version 9.0

Medication DAPT

Medication - DAPT

ASA/DAPT
cmplt

Other ASA/DAPT
cmpltt

Additional anti-platelet/anti-coagulation therapy ? ○ Yes ○ No
cmplt2

If additional anti-platelet/anti-coagulation therapy, please specify:
cmplt2t

Start

Start date
cmpltstdtc
(First day the stated medication was taken by patient)

Start date is ○ Exact ○ Day unknown ○ Month and Day unknown ○ Unknown
cmpltstdtcsts

Reason for start
cmpltstrn

Other reason for start
cmpltstrnt

Stop

Stop date
(Last day the stated medication was taken by patient)

Stop date is ○ Exact

cmpltendtc

- Day unknown
- Month and Day unknown
- Unknown

cmpltendtcsts

Reason for stop

cmpltenrn

Other reason for stop

cmpltenrnt

Current visit is

visit

cmplt - ASA/DAPT - 102426

Choice Text | *Encoded Value*

ASA + Clopidogrel | 1
ASA + Ticlopidine | 2
ASA + Prasugrel | 3
ASA + Ticagrelor | 4
ASA + Other | 5
ASA only | 6
Other (single or combination) | 99

cmplt2 - Additional anti-platelet/anti-coagulation therapy ? - 102428

Choice Text | *Encoded Value*

Yes | 1
No | 0

cmpltendtcsts - Stop date is - 102437

Choice Text | *Encoded Value*

Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 4

cmpltenrn - Reason for stop - 102434

Choice Text | *Encoded Value*

According to standard therapy | 1
Other | 99

cmpltstdtcsts - Start date is - 102436

Choice Text | *Encoded Value*

Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 4

cmpltstrn - Reason for start - 102431

Choice Text | *Encoded Value*

Initial medication due to treatment of target lesion | 1
Re-start of target lesion medication after interruption | 2
Change in target lesion medication without interruption | 3
Additional vascular intervention | 4
Standard ASA therapy | 5
Other reason | 99

Form Name	Community
Medication Statins	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Medication Log	CAVI C1503 BIOSOLVE-IV Version 9.0

Medication Statins

Medication - Statins

Start date (First day the stated medication was taken by patient)
cmstatinsstdtc

Start date is
- Exact
- Day unknown
- Month and Day unknown
- Unknown

cmstatinsstdtcsts

Stop date (Last day the stated medication was taken by patient)
cmstatinsendtc

Stop date is
- Exact
- Day unknown
- Month and Day unknown
- Unknown

cmstatinsendtcsts

Current visit is
visit

cmstatinsendtcsts - Stop date is - 102441

Choice Text | *Encoded Value*

Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 4

cmstatinsstdtcsts - Start date is - 102440

Choice Text | *Encoded Value*

Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 4

Form Name	Community
Additional Information Log	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Additional Information Log

Current visit is

visit

Additional Information Log

See additional_information

Form Name	Community
Additional Information	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Additional Information Log	CAVI C1503 BIOSOLVE-IV Version 9.0

Additional Information

Additional Information

Visit

visit

Comments

comments

visit - Visit - 102195

Choice Text | *Encoded Value*

Screening | 11
Procedure | 21
Hospital Discharge | 100
6-Month Follow-up | 306
12-Month Follow-up | 312
2-Year Follow-up | 402
3-Year Follow-up | 403
4-Year Follow-up | 404
5-Year Follow-up | 405

Form Name	Community
Protocol Deviation Log	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Protocol Deviation Log

Protocol Deviation Log

Current visit is

visit

See protocol_deviation

Form Name	Community
Protocol Deviation	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Protocol Deviation Log	CAVI C1503 BIOSOLVE-IV Version 9.0

Protocol Deviation

Protocol Deviation

Visit
visit

Category Screening
pdcatscreen

Category Procedure
pdcatproc

Category Follow-up
pdcatfup

Category
pdcat

Other category
pdcatt

Reason for occurrence
- Patient refusal
- Patient unable to tolerate testing
- Not possible due to technical reasons
- Not possible due to organisational reasons
- Other

pdrn

Other reason
pdrnt

Corrective action	pdcoract
Current visit is	visitx

pdcatfup - Category Follow-up - 102217

Choice Text | *Encoded Value*

Visit not done | 400
Visit out of time window | 401
Ischemic status not assessed | 402
Other | 99

pdcatproc - Category Procedure - 102215

Choice Text | *Encoded Value*

Two stents used to treat one lesion | 203
Study device: inappropriate length and / or diameter to treat target lesion | 206
Dissection treated with incorrect device | 207
Post-dilation with other device than un-coated balloon | 208
Pre- and or post-dilation: inappropriate length and / or diameter to treat target lesion | 209
ECG not done | 210
Other | 99

pdcatscreen - Category Screening - 102214

Choice Text | *Encoded Value*

No signed consent prior to treatment | 1
Inclusion Criteria not fulfilled | 110
Exclusion Criteria not fulfilled | 111
Fertility test not done | 119
LVEF test not done | 121
Other | 99

pdrn - Reason for occurrence - 102004

Choice Text | *Encoded Value*

Patient refusal | 1
Patient unable to tolerate testing | 2
Not possible due to technical reasons | 3
Not possible due to organisational reasons | 4
Other | 99

visit - Visit - 102199

Choice Text | *Encoded Value*

Screening | 11
Procedure | 21
Hospital Discharge | 100
6-Month Follow-up | 306
12-Month Follow-up | 312
2-Year Follow-up | 402
3-Year Follow-up | 403
4-Year Follow-up | 404

5-Year Follow-up | 405

Form Name	Community
Device Deficiency Log	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Device Deficiency Log

Current visit is

visit

Device Deficiency Log

See device_deficiency

Form Name	Community
Device Deficiency	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Device Deficiency Log	CAVI C1503 BIOSOLVE-IV Version 9.0

Device Deficiency

Device Deficiency

Visit
visit

Date of device deficiency
dfdtc

Name of device affected
dfnme

Reference number
dfref

Batch/Lot number
dflot

Time of device deficiency
- Pre-procedure
- During procedure
- After procedure

dftme

Is the device deficiency related to an adverse event ?
Yes No
dfrelae

Number of related AE
dfaeid

Description of device deficiency

dfterm

Could the device deficiency have led to an Serious Adverse Event if suitable action had not been taken or intervention had not been made or if circumstances had been less fortunate ? ◯ Yes ◯ No
dfsade

If yes, please describe:

dfsadet

Is the device deficiency related to a BIOTRONIK device ? ◯ Yes ◯ No
dfrelbio

Has the complaint notification form been sent to BIOTRONIK AG ? ◯ Yes ◯ No
dfcntobio

If yes, please attach a copy of the complaint notification form Upload Available on Existing Forms
dfcndoc

Note: The upload link is shown after saving of this record.

Has the affected device been returned to BIOTRONIK AG ? ◯ Yes ◯ No
dfdevtobio

Other comments (optional):

dfrelbiot

dfcntobio - Has the complaint notification form been sent to BIOTRONIK AG ? - 102684
Choice Text | *Encoded Value*
Yes | 1
No | 0

dfdevtobio - Has the affected device been returned to BIOTRONIK AG ? - 102686
Choice Text | *Encoded Value*
Yes | 1
No | 0

dfrelae - Is the device deficiency related to an adverse event ? - 102678
Choice Text | *Encoded Value*
Yes | 1
No | 0

dfrelbio - Is the device deficiency related to a BIOTRONIK device ? - 102683
Choice Text | *Encoded Value*
Yes | 1
No | 0

dfsade - Could the device deficiency have led to an Serious Adverse Event if suitable action had not been taken or intervention had not been made or if circumstances had been less fortunate ? - 102681
Choice Text | *Encoded Value*
Yes | 1
No | 0

dftme - Time of device deficiency - 102677
Choice Text | *Encoded Value*
Pre-procedure | 1
During procedure | 2
After procedure | 3

visit - Visit - 102672
Choice Text | *Encoded Value*
Screening | 11
Procedure | 21
Hospital Discharge | 100
6-Month Follow-up | 306
12-Month Follow-up | 312
2-Year Follow-up | 402
3-Year Follow-up | 403
4-Year Follow-up | 404
5-Year Follow-up | 405

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 and 2.0 and 3.0 enrolled subjects
[see 3.0-specific fields indicated below, which are also shown for new records of 2.0-subjects at 3.0-sites]

Adverse Event
Event Date

Current visit is
visit

Adverse Event

Start/Stop Date not exactly known:
If **Day** is unknown: enter **15** for **Day**
If **Day** and **Month** are unknown: enter **01JUL** for **Day** and **Month**

Event number (autopopulated by system)
aeid

aestdtc_intnum

Start date
aestdtc

Start date is
- Exact
- Day unknown
- Month and Day unknown
- Unknown

aestdtcsts

intermittent
aeintermit

Date of awareness
aeawaredtc

Date of awareness is
- Exact
- Day unknown
- Month and Day unknown
- Unknown

aeawdtcsts

Type of contact
- Inpatient
- Outpatient
- Telephone
- Other communication method

aecntacttype

Please specify "Other communication method":
aecntacttypet

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Death & MI

Death

Death ? ◯ Yes ◯ No
aedth

Death category ◯ Cardiac ◯ Non-cardiac ◯ Unknown
aedthcs

Date of death
aedthdtc

Myocardial Infarction

MI acc. to Universal Definition ? ◯ Yes ◯ No
aemiudef

MI acc. to Universal Definition - Timing ◯ Periprocedural ◯ Spontaneous ◯ Reinfarction ◯ Sudden death ◯ Unknown
aemiudeftm

MI acc. to Extended Historical Definition ? ◯ Yes ◯ No
aemiehdef

MI acc. to Extended Historical Definition - Timing ◯ Periprocedural ◯ Spontaneous ◯ Reinfarction ◯ Sudden death ◯ Unknown
aemiehdeftm

MI acc. to SCAI definition ? ◯ Yes ◯ No

aemiscaidef

Caused by target vessel ? ○ Yes ○ No ○ Unknown

aemibytv

Date of MI

aemidtc

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

CABG&Stent/Scaffold Thrombosis

CABG

Coronary artery by-pass graft ? ○ Yes ○ No
aecabg

Emergent CABG ? ○ Yes ○ No
aecabgemerg

Date of CABG
aecabgdtc

Stent/Scaffold Thrombosis

Stent/scaffold thrombosis ? ○ Yes ○ No
aestthrmb

Date of stent/scaffold thrombosis
aestthrmbdtc

Indicate for which device
aestthrmbdev

Date of implantation
aestimpldtc

Classification
- ○ Acute (<= 24 hours)
- ○ Sub-acute (> 24 hours and <= 30 days)
- ○ Late (> 30 days and <= 1 year)
- ○ Very late (> 1 year)

aestthrmbtm

Category
- ○ Possible
- ○ Probable
- ○ Definite
- ○ Unknown

aestthrmbcs

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Revascularization & Trigger

Revascularization

Revascularization
- No
- Target lesion revascularization
- Target vessel revascularization
- Non-target vessel revascularization

aerevasc

Date of revascularization

aerevascdtc

CIP 3.0 sites (2.0 and 3.0 subjects)

FFR done? Yes No

aeffrdn_3

FFR result

aeffrval_3

ID of related target lesion 1 2

lcid

Clinically driven ? Yes No Unknown

aerevasccld

Note: Please indicate the triggering event.
- In case only one event occurred, please select the corresponding event.
- If multiple events occurred please select the event that occurred first in time.

Triggering event
- MI
- CABG
- Stent/scaffold thrombosis
- TLR
- TVR
- Non-TVR

aetrigger

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Other Event & Narrative

Other Event

Other event

aeother

Narrative - Event / Treatment / Outcome (please give detailed description of event)

Narrative

aeterm

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Seriousness & Actions Taken

Did the AE fulfill any of the below criteria?

Death ? ○ Yes ○ No
aeseris1

Foetal distress, foetal death, or congenital abnormality or birth defect ? ○ Yes ○ No
aeseris2

Serious deterioration in the health of the patient that resulted in

A life threatening situation ? ○ Yes ○ No
aeseris3

Hospitalization or prolongation of existing hospitalization ? ○ Yes ○ No
aeseris4

Permanent impairment of a body structure/body function ? ○ Yes ○ No
aeseris5

Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure/body function ? ○ Yes ○ No
aeseris6

If any of the above questions have been answered YES, the adverse event is classified as SERIOUS

Date event became serious
aesaedtc

☐ same as start date
aesaedtc2

Actions Taken

Any diagnostic or therapeutic actions taken ? ○ Yes ○ No
aeacn

Diagnostic and Therapeutic Actions Table

See actions_taken

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Outcome and Relationship

Outcome

- Resolved
- Resolved with sequelae
- Ongoing
- Patient died

aeout

Stop date

aeendtc

Stop date is

- Exact
- Day unknown
- Month and Day unknown
- Unknown

aeendtcsts

Relationship

Relation to **device**

- Not related
- Unlikely
- Possible
- Probable
- Causal relationship

aereldev

Type of relation to device

- Clinical reason
- User error
- Device deficiency

aereldevrn

Relation to **procedure**

- Not related
- Unlikely
- Possible
- Probable
- Causal relationship

aerelprc

Event is

- Anticipated
- Unanticipated

aeantcip

Anticipated: event is listed in IFU (Information for use)
Unanticipated: event is NOT listed in IFU

Set by System

Event category

Event code

Days post procedure

aetype aecode aedays

aeacn - Any diagnostic or therapeutic actions taken ? - 102527
Choice Text | *Encoded Value*
Yes | 1
No | 2

aeantcip - Event is - 102516
Choice Text | *Encoded Value*
Anticipated | 1
Unanticipated | 2

aeawdtcsts - Date of awareness is - 102722
Choice Text | *Encoded Value*
Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 100

aecabg - Coronary artery by-pass graft ? - 102543
Choice Text | *Encoded Value*
Yes | 1
No | 0

aecabgemerg - Emergent CABG ? - 102544
Choice Text | *Encoded Value*
Yes | 1
No | 0

aecntacttype - Type of contact - 102094
Choice Text | *Encoded Value*
Inpatient | 1
Outpatient | 2
Telephone | 3
Other communication method | 99

aedth - Death ? - 102535
Choice Text | *Encoded Value*
Yes | 1
No | 0

aedthcs - Death category - 102536
Choice Text | *Encoded Value*
Cardiac | 1
Non-cardiac | 2

Unknown | 100

aeendtcsts - Stop date is - 102518
Choice Text | *Encoded Value*
Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 100

aeffrdn_3 - FFR done? - 103445
Choice Text | *Encoded Value*
Yes | 1
No | 0

aemibytv - Caused by target vessel ? - 102541
Choice Text | *Encoded Value*
Yes | 1
No | 0
Unknown | 100

aemiehdef - MI acc. to Extended Historical Definition ? - 102539
Choice Text | *Encoded Value*
Yes | 1
No | 0

aemiehdeftm - MI acc. to Extended Historical Definition - Timing - 102540
Choice Text | *Encoded Value*
Periprocedural | 1
Spontaneous | 2
Reinfarction | 3
Sudden death | 4
Unknown | 100

aemiscaidef - MI acc. to SCAI definition ? - 102670
Choice Text | *Encoded Value*
Yes | 1
No | 0

aemiudef - MI acc. to Universal Definition ? - 102537
Choice Text | *Encoded Value*
Yes | 1
No | 0

aemiudeftm - MI acc. to Universal Definition - Timing - 102538

Choice Text | *Encoded Value*
Periprocedural | 1
Spontaneous | 2
Reinfarction | 3
Sudden death | 4
Unknown | 100

aeother - Other event - 102558

Choice Text | *Encoded Value*
Acute Coronary Syndrome | 1
Allergic Reaction | 2
Aneurysm | 4
Angina | 5
Arrhythmia | 6
Atypical Chest Pain | 7
Cancer | 8
Cardiac Tamponade | 10
Cardiogenic Shock | 11
Chronic Heart Failure | 12
Diabetes | 16
Dissection | 17
Fainting/Syncope | 18
Fracture (Bone) | 19
Gastrointestinal Disorder | 21
Hematological Disorder | 22
Hematoma/Bleeding | 23
Hypertension | 24
Infection | 25
Inflammation | 26
Metabolic Disorder | 27
Neurologic Disorder | 28
Non-study Device Malfunction | 31
Pain (Skeltal, Spine, Muscular) | 32
Peripheral Artery Disease | 33
Pseudoaneurysm | 34
Puncture Site Complication | 35
Renal Disorder | 36
Respiratory Disorder | 37
Restenosis - Target Lesion | 38
Restenosis - Target Vessel | 39
Restenosis Non-Target Vessel | 40
Stenosis - De Novo | 41
Study Device Malfunction | 43
Thromboembolism | 44
Urinary Disorder | 46
Vasospasm | 47

Worsening of General Condition | 48
Other | 99

aeout - Outcome - 102512

Choice Text | *Encoded Value*

Resolved | 1
Resolved with sequelae | 2
Ongoing | 3
Patient died | 4

aereldev - Relation to device - 102514

Choice Text | *Encoded Value*

Not related | 0
Unlikely | 1
Possible | 2
Probable | 3
Causal relationship | 4

aereldevrn - Type of relation to device - 102517

Choice Text | *Encoded Value*

Clinical reason | 1
User error | 2
Device deficiency | 3

aerelprc - Relation to procedure - 102515

Choice Text | *Encoded Value*

Not related | 0
Unlikely | 1
Possible | 2
Probable | 3
Causal relationship | 4

aerevasc - Revascularization - 102553

Choice Text | *Encoded Value*

No | 0
Target lesion revascularization | 1
Target vessel revascularization | 2
Non-target vessel revascularization | 3

aerevasccld - Clinically driven ? - 102556

Choice Text | *Encoded Value*

Yes | 1
No | 0
Unknown | 100

aeseris1 - Death ? - 102519
Choice Text | Encoded Value
Yes | 1
No | 0

aeseris2 - Foetal distress, foetal death, or congenital abnormality or birth defect ? - 102520
Choice Text | Encoded Value
Yes | 1
No | 0

aeseris3 - A life threatening situation ? - 102521
Choice Text | Encoded Value
Yes | 1
No | 0

aeseris4 - Hospitalization or prolongation of existing hospitalization ? - 102522
Choice Text | Encoded Value
Yes | 1
No | 0

aeseris5 - Permanent impairment of a body structure/body function ? - 102523
Choice Text | Encoded Value
Yes | 1
No | 0

aeseris6 - Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure/body function ? - 102524
Choice Text | Encoded Value
Yes | 1
No | 0

aestdtcsts - Start date is - 102511
Choice Text | Encoded Value
Exact | 1
Day unknown | 2
Month and Day unknown | 3
Unknown | 100

aestthrmb - Stent/scaffold thrombosis ? - 102546
Choice Text | Encoded Value
Yes | 1
No | 0

aestthrmbcs - Category - 102551

Choice Text | *Encoded Value*

Possible | 1
Probable | 2
Definite | 3
Unknown | 100

aestthrmbtm - Classification - 102550

Choice Text | *Encoded Value*

Acute (<= 24 hours) | 1
Sub-acute (> 24 hours and <= 30 days) | 2
Late (> 30 days and <= 1 year) | 3
Very late (> 1 year) | 4

aetrigger - Triggering event - 102552

Choice Text | *Encoded Value*

MI | 4
CABG | 5
Stent/scaffold thrombosis | 6
TLR | 7
TVR | 8
Non-TVR | 9

lcid - ID of related target lesion - 102555

Choice Text | *Encoded Value*

1 | 1
2 | 2

Form Name	Community
Actions Taken	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
Adverse Event	CAVI C1503 BIOSOLVE-IV Version 9.0

Actions Taken

Actions Taken

Event number
aeid

Type of action
- Diagnostic
- Medication therapy
- Non-medication therapy

aeacntype

Description of action
aeacnterm

Date action taken
aeacndtc

Diagnostic findings / Therapy result / Comments
aeacnres

Current visit is
visit

aeacntype - Type of action - 101965

Choice Text | Encoded Value

Diagnostic | 1
Medication therapy | 2
Non-medication therapy | 3

Form Name	Community
CEC Document Collection	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

CEC Document Collection
Document Collection

CEC Source Document Collection

BIOTRONIK User Note: You must save this blank form before requesting documents from the site.

Initial Review of AE

Event number

aeid

CEC adjudication required?

Yes
No
CEC_Required

Yes will set the adjudication status to "Pending Document Collection" and will move this AE to the "Site CEC Report"

No will set the adjudication status to "Not Adjudicated" and will move this AE to the "No CEC Report"

Document Submission from Site to BIOTRONIK

1.1 - 1.4 to be completed by **BIOTRONIK**
2.1 - 2.4 to be completed by **Site**

See cec_doc_table

Document submission complete? Yes No Additional info required
CEC_Sub_Complete

SO only:

Document collection complete? Yes No
CEC_Collection_Complete

Ready for adjudication? ○ Yes ○ No
CEC_Ready_Adjudication

Yes sets the CEC adjudication status to "Pending Adjudication" and moves this AE to the "CEC Report(s)".

Adjudication complete? ○ Yes ○ No
CEC_Adjudication_Complete

Yes moves this AE to the "Final CEC Report".

If adjudicated by more than one CEC member:
The CEC adjudication status is set to "Adjudicated" by the system once user agreement is reached.

Important: Never change the answers to the four questions above during re-adjudication!

Form Name	Community
CEC Document Collection	CAVI C1503 BIOSOLVE-IV Version 9.0

SO Notes / Re-adjudication

Safety Officer Notes

SO Notes

CEC_SO_Notes

Re-adjudication

Current re-adjudication status

- SDC: Document collection at site
- CEC: Re-adjudication by CEC
- END: Re-adjudication complete

CEC_Readjudication_Status

SDC moves this AE to the "Site CEC Report" for document upload by the site.

CEC moves this AE to the "CEC Report(s)" for re-adjudication by the CEC member(s).

END moves this AE to the "Final CEC Report".

1st Re-adjudication

☐ 1st Re-adjudication requested

CEC_Readjudication_1

Date

CEC_Readjudication_1_Date

Reason

CEC_Readjudication_1_Reason

2nd Re-adjudication

☐ 2nd Re-adjudication requested

CEC_Readjudication_2

Date

CEC_Readjudication_2_Date

Reason

CEC_Readjudication_2_Reason

Form Name	Community
CEC Document Collection	CAVI C1503 BIOSOLVE-IV Version 9.0

Notifications

Safety Officer: Please check CEC members for participation in the adjudication process.
Notification(s) will be sent automatically by the system via e-mail.

- ☐ send e-mail to CEC DMC member 1
  cecmem1
- ☐ send e-mail to CEC DMC member 2
  cecmem2
- ☐ send e-mail to CEC DMC member 3
  cecmem3

CEC_Adjudication_Complete - Adjudication complete? - 103362
Choice Text | Encoded Value
Yes | 1
No | 0

CEC_Collection_Complete - Document collection complete? - 102052
Choice Text | Encoded Value
Yes | 1
No | 0

CEC_Readjudication_Status - Current re-adjudication status - 103432
Choice Text | Encoded Value
SDC: Document collection at site | 1
CEC: Re-adjudication by CEC | 2
END: Re-adjudication complete | 3

CEC_Ready_Adjudication - Ready for adjudication? - 102053
Choice Text | Encoded Value
Yes | 1
No | 0

CEC_Required - CEC adjudication required? - 102752
Choice Text | Encoded Value
Yes | 1
No | 0

CEC_Sub_Complete - Document submission complete? - 102051
Choice Text | Encoded Value
Yes
No
Additional info required

Form Name	Community
CEC Document Collection Table	CAVI C1503 BIOSOLVE-IV Version 9.0

Parent Form Details

Form Name	Community
CEC Document Collection	CAVI C1503 BIOSOLVE-IV Version 9.0

CEC Document Collection Table

1. To be completed by **Sponsor**

1.1 Document Required

DOC_Document_Required

1.2 Date CD sent to CEC

DOC_Date_CD_to_CEC

1.3 BIOTRONIK Comments

DOC_BIO_Comments

☐ 1.4 Not for use by CEC

DOC_Not_for_CEC

2. To be completed by **Site**

2.1 Submission Method

DOC_Submission_Method

2.2 Date Submitted

DOC_Date_Submitted

2.3 Site Comments

	DOC_Site_Comments
2.4 Document upload (20 MB max per doc)	Upload Available on Existing Forms DOC_Uploaded

DOC_Document_Required - 1.1 Document Required - 102043

Choice Text | *Encoded Value*

Cath Lab report | 1
Death Certificate | 2
Images | 3
Medical Records/Discharge Letter | 4
Other | 99

DOC_Submission_Method - 2.1 Submission Method - 102047

Choice Text | *Encoded Value*

Courier | 1
Email | 2
Fax | 3
Upload | 4
Other | 99
Not available | 100

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

CIP 1.0 & 2.0 & 3.0 enrolled subjects

Event Adjudication
Death & MI

Event Adjudication by CEC

Current visit is
visit

Event number (autopopulated by system)
aeid

CEC DMC member (autopopulated by system)
ccid

Name or initials of CEC member
ccname

Adjudication complete ? ○ Yes ○ No
cccomplete

Date of adjudication
ccdtc

Death

Death ? ○ Yes ○ No
ccdth

Death category
○ Cardiac
○ Non-cardiac
○ Unknown
ccdthcs

Date of death
ccdthdtc

Myocardial Infarction

MI acc. to Universal Definition ?	○ Yes ○ No ccmiudef
MI acc. to Universal Definition - Timing	○ Periprocedural ○ Spontaneous ○ Reinfarction ○ Sudden death ○ Unknown ccmiudeftm
MI acc. to Extended Historical Definition ?	○ Yes ○ No ccmiehdef
MI acc. to Extended Historical Definition - Timing	○ Periprocedural ○ Spontaneous ○ Reinfarction ○ Sudden death ○ Unknown ccmiehdeftm
MI acc. to SCAI definition ?	○ Yes ○ No ccmiscaidef
Caused by target vessel ?	○ Yes ○ No ○ Unknown ccmibytv
Date of MI	[ ] ccmidtc

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

CABG&Stent/Scaffold Thrombosis

CABG

Coronary artery by-pass graft ? ◯ Yes ◯ No
cccabg

Emergent CABG ? ◯ Yes ◯ No
cccabgemerg

Date of CABG
cccabgdtc

Stent/Scaffold Thrombosis

Stent/scaffold thrombosis ? ◯ Yes ◯ No
ccstthrmb

Date of stent/scaffold thrombosis
ccstthrmbdtc

Indicate for which device
ccstthrmbdev

Date of implantation
ccstimpldtc

Classification
◯ Acute (<= 24 hours)
◯ Sub-acute (> 24 hours and <= 30 days)
◯ Late (> 30 days and <= 1 year)
◯ Very late (> 1 year)
ccstthrmbtm

Category
◯ Possible
◯ Probable
◯ Definite
◯ Unknown

ccstthrmbcs

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

Revascularization & Trigger

Revascularization

Revascularization
- ○ No
- ○ Target lesion revascularization
- ○ Target vessel revascularization
- ○ Non-target vessel revascularization

ccrevasc

Date of revascularization

ccrevascdtc

ID of related target lesion ○ 1 ○ 2

lcid

Clinically driven ? ○ Yes ○ No ○ Unknown

ccrevasccld

Note: Please indicate the triggering event.
- In case only one event occurred, please select the corresponding event.
- If multiple events occurred please select the event that occurred first in time.

Triggering event
- ○ MI
- ○ CABG
- ○ Stent/scaffold thrombosis
- ○ TLR
- ○ TVR
- ○ Non-TVR

cctrigger

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

Other Event & Comments

Other Event

Other event

ccother

Comments (please give detailed description of event)

Comments

cccomm

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

Seriousness

Did the AE fulfill any of the below criteria?

Death ? ◯ Yes ◯ No
ccseris1

Foetal distress, foetal death, or congenital abnormality or birth defect ? ◯ Yes ◯ No
ccseris2

Serious deterioration in the health of the patient that resulted in

A life threatening situation ? ◯ Yes ◯ No
ccseris3

Hospitalization or prolongation of existing hospitalization ? ◯ Yes ◯ No
ccseris4

Permanent impairment of a body structure/body function ? ◯ Yes ◯ No
ccseris5

Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure/body function ? ◯ Yes ◯ No
ccseris6

If any of the above questions have been answered YES, the adverse event is classified as SERIOUS

Form Name	Community
Event Adjudication	CAVI C1503 BIOSOLVE-IV Version 9.0

Relationship & Category

Relationship

Relation to **device**
- Not related
- Unlikely
- Possible
- Probable
- Causal relationship

ccreldev

Type of relation to device
- Clinical reason
- User error
- Device deficiency

ccreldevrn

Relation to **procedure**
- Not related
- Unlikely
- Possible
- Probable
- Causal relationship

ccrelprc

Event is
- Anticipated
- Unanticipated

ccantcip

Anticipated: event is listed in IFU (Information for use)
Unanticipated: event is NOT listed in IFU

Set by System

Event category _____ cctype

Event code _____ cccode

ccantcip - Event is - 103145
Choice Text | Encoded Value
Anticipated | 1
Unanticipated | 2

cccabg - Coronary artery by-pass graft ? - 103114
Choice Text | Encoded Value
Yes | 1
No | 0

cccabgemerg - Emergent CABG ? - 103115
Choice Text | Encoded Value
Yes | 1
No | 0

cccomplete - Adjudication complete ? - 103431
Choice Text | Encoded Value
Yes | 1
No | 0

ccdth - Death ? - 103104
Choice Text | Encoded Value
Yes | 1
No | 0

ccdthcs - Death category - 103105
Choice Text | Encoded Value
Cardiac | 1
Non-cardiac | 2
Unknown | 100

ccmibytv - Caused by target vessel ? - 103112
Choice Text | Encoded Value
Yes | 1
No | 0
Unknown | 100

ccmiehdef - MI acc. to Extended Historical Definition ? - 103109
Choice Text | Encoded Value
Yes | 1
No | 0

ccmiehdeftm - MI acc. to Extended Historical Definition - Timing - 103110

Choice Text | *Encoded Value*
Periprocedural | 1
Spontaneous | 2
Reinfarction | 3
Sudden death | 4
Unknown | 100

ccmiscaidef - MI acc. to SCAI definition ? - 103111
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccmiudef - MI acc. to Universal Definition ? - 103107
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccmiudeftm - MI acc. to Universal Definition - Timing - 103108
Choice Text | *Encoded Value*
Periprocedural | 1
Spontaneous | 2
Reinfarction | 3
Sudden death | 4
Unknown | 100

ccother - Other event - 103128
Choice Text | *Encoded Value*
Acute Coronary Syndrome | 1
Allergic Reaction | 2
Aneurysm | 4
Angina | 5
Arrhythmia | 6
Atypical Chest Pain | 7
Cancer | 8
Cardiac Tamponade | 10
Cardiogenic Shock | 11
Chronic Heart Failure | 12
Diabetes | 16
Dissection | 17
Fainting/Syncope | 18
Fracture (Bone) | 19
Gastrointestinal Disorder | 21
Hematological Disorder | 22
Hematoma/Bleeding | 23
Hypertension | 24

Infection | 25
Inflammation | 26
Metabolic Disorder | 27
Neurologic Disorder | 28
Non-study Device Malfunction | 31
Pain (Skeltal, Spine, Muscular) | 32
Peripheral Artery Disease | 33
Pseudoaneurysm | 34
Puncture Site Complication | 35
Renal Disorder | 36
Respiratory Disorder | 37
Restenosis - Target Lesion | 38
Restenosis - Target Vessel | 39
Restenosis Non-Target Vessel | 40
Stenosis - De Novo | 41
Study Device Malfunction | 43
Thromboembolism | 44
Urinary Disorder | 46
Vasospasm | 47
Worsening of General Condition | 48
Other | 99

ccreldev - Relation to device - 103142

Choice Text | *Encoded Value*

Not related | 0
Unlikely | 1
Possible | 2
Probable | 3
Causal relationship | 4

ccreldevrn - Type of relation to device - 103143

Choice Text | *Encoded Value*

Clinical reason | 1
User error | 2
Device deficiency | 3

ccrelprc - Relation to procedure - 103144

Choice Text | *Encoded Value*

Not related | 0
Unlikely | 1
Possible | 2
Probable | 3
Causal relationship | 4

ccrevasc - Revascularization - 103123

Choice Text | *Encoded Value*
No | 0
Target lesion revascularization | 1
Target vessel revascularization | 2
Non-target vessel revascularization | 3

ccrevasccld - Clinically driven ? - 103126
Choice Text | *Encoded Value*
Yes | 1
No | 0
Unknown | 100

ccseris1 - Death ? - 103130
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccseris2 - Foetal distress, foetal death, or congenital abnormality or birth defect ? - 103131
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccseris3 - A life threatening situation ? - 103132
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccseris4 - Hospitalization or prolongation of existing hospitalization ? - 103133
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccseris5 - Permanent impairment of a body structure/body function ? - 103134
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccseris6 - Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure/body function ? - 103135
Choice Text | *Encoded Value*
Yes | 1
No | 0

ccstthrmb - Stent/scaffold thrombosis ? - 103117

Choice Text | *Encoded Value*
Yes | 1
No | 0

ccstthrmbcs - Category - 103122
Choice Text | *Encoded Value*
Possible | 1
Probable | 2
Definite | 3
Unknown | 100

ccstthrmbtm - Classification - 103121
Choice Text | *Encoded Value*
Acute (<= 24 hours) | 1
Sub-acute (> 24 hours and <= 30 days) | 2
Late (> 30 days and <= 1 year) | 3
Very late (> 1 year) | 4

cctrigger - Triggering event - 103127
Choice Text | *Encoded Value*
MI | 4
CABG | 5
Stent/scaffold thrombosis | 6
TLR | 7
TVR | 8
Non-TVR | 9

lcid - ID of related target lesion - 103125
Choice Text | *Encoded Value*
1 | 1
2 | 2