# User manual: SwissCaRe in CardioReport XP

| Document             |                   |
|----------------------|-------------------|
| Document prepared by | Mohamed EL KADI   |
| Version              | 2.0               |
| First version        | 1.0               |
| Last update          | 09/01/2024        |
|                      |                   |
| Validated by         | Fabrice BEVERELLI |

#### Historique des versions

| Doc. Version | Modifications | Module version | Date       | Author  |
|--------------|---------------|----------------|------------|---------|
| 1.0          | Creation      |                | 28/11/2021 | Mohamed |
| 2.0          | Creation      |                | 09/01/2024 | Mohamed |

#### **Changes Version 2.0**

- New chapter VI PCI aborted added
- Chapter XII Calcium modification updated
- New chapter XIII Major complications added

MediReport shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this publication. MediReport reserves the right to revise this publication and to make changes to its content at any time, without obligation to notify any person or entity of such revisions and changes.

This publication may only be used in connection with the promotion, sales, installation and use of MediReport equipment by MediReport personnel. The information presented herein is sensitive and is classified Company Confidential. Without written authority from the proprietor, further distribution outside the company is not allowed.

Copyright © Febryary 2012 MediReport All rights reserved.

# Summary

| I-    | SwissCare Form  | 4  |
|-------|---|----|
| II-   | Patient data / consent  | 5  |
| III-  | Indication  | 6  |
| IV-   | Resting index (iFR/RFR) & FFR   | 8  |
| V-    | IVUS/OCT  | 8  |
| VI-   | PCI aborted   | 9  |
| VII-  | Number of treated lesions & vessels                                   | 9  |
| VIII- | Number of implanted stents & used drug-eluting balloons               | 9  |
| IX-   | Restenosis & Stent Thrombosis   | 10 |
| X-    | CTO procedure   | 11 |
| XI-   | Bifurcation   | 11 |
| XII-  | Calcium modification (Rotablation, Lithotripsy, Orbital Atherectomy,) | 12 |
| XIII- | SwissCaRe Protocol  | 13 |
| XIV-  | Important notes   | 14 |

#### I- SwissCare Form

The SwissCaRe form is present as additional tab in CardioReport for all angiographies and PCIs.

The SwissCaRe form summarizes all questions that need to be answered.

In general, all visible fields are mandatory in SwissCaRe.

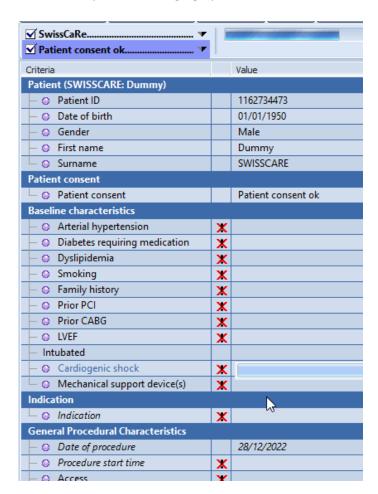
Missing entries are highlighted:

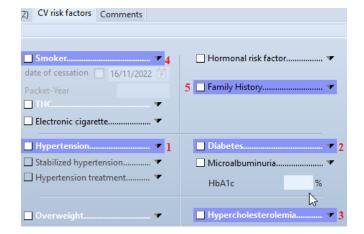
**Note:** The questionnaire will vary depending on the procedure (Angio, PCI, Angio & PCI). Additionally, certain answers can cause additional questions to appear (e.g. indication = ACS or CAD).

A double-click on the question brings you to the CardioReport tab in which the question can be filled in.

Most questions can also be filled in the SwissCaRe form.

SwissCaRe questions are highlighted in CardioReport.



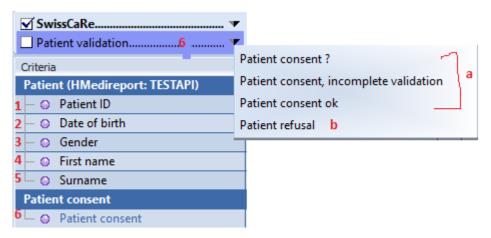


# **II- Patient data / consent**

SwissCaRe requires the variables **1-5** for patient information. Patient data is entered under "administrative data" in CardioReport. (**PID** is a unique code for each patient)



Transfer of personal data requires **patient consent (6)**. Patient consent status is indicated in the SwissCaRe form in CardioReport:



**6-a-** If patient consent is "Patient consent ok" or "Patient consent?" or "Patient consent, incomplete validation" patient data is transferred to SwissCaRe without anonymization.

**6-b-** If patient consent is **"Patient refusal"** patient data will be sent to SwissCaRe in an anonymized way:

5/4- Last name / First name as "NoConsent"

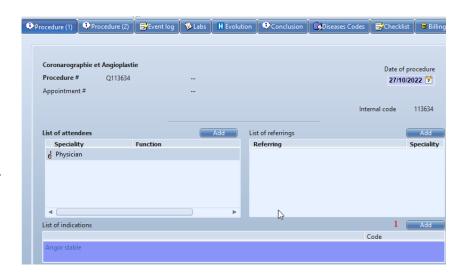
2- Date of birth will be in the format 1st January plus the year of birth

# **III- Indication**

The indication for the angiography or PCI is an important gateway variable in SwissCaRe.

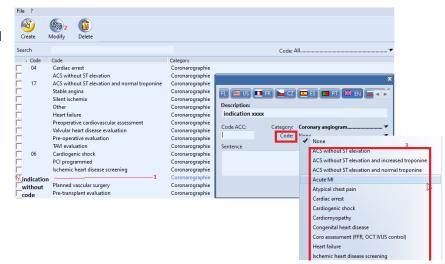
The indication needs to be entered in the Procedure (1) page in CardioReport -> List of indications -> click "add" button (1).

**Note:** In CardioReport several indications can be entered, but only the indication on the top of the list will be transferred to the SwissCaRe form.



Important: Indications can be added or modified by each hospital.

Therefore, each indication (1) needs to be matched to an indication code (2,3), which are fixed in CardioReport. This should be done once and then modification of indications should be locked by the responsible of the hospital.



Below the SwissCaRe indications are listed with the corresponding indication codes in CardioReport:

Clinical presentation as ACS

| FR-Description                        | EN-Description                                   |
|---------------------------------------|--|
| SCA ST- avec troponine normale        | ACS without ST elevation and normal troponine    |
| SCA ST- avec troponine élevée         | ACS without ST elevation and increased troponine |
| SA ST+ infarctus phase aigüe          | Acute MI   |
| Infarctus semi-récent thrombolysé     | Subacute MI thrombolyzed                         |
| Infarctus semi-récent non thrombolysé | Subacute MI not thrombolyzed                     |
| SCA ECG et troponine normale          | ACS without ST elevation                         |

• Suspected CAD or suspected progression of known CAD

| FR-Description           | EN-Description                   |
|--------------------------|----------------------------------|
| Dépistage coronaropathie | Ischemic heart disease screening |
| Douleurs atypiques       | Atypical chest pain              |
| Ischémie silencieuse     | Silent ischemia                  |
| Angor stable             | Stable angina                    |
| Cardiomyopathie          | Cardiomyopathy                   |
| Cardiopathie congénitale | Congenital heart disease         |
| Autre ischémie           | Other ischemia                   |

#### • Planned valvular heart disease intervention

| FR-Description      | EN-Description                    |
|---------------------|-----------------------------------|
| Bilan valvulopathie | Valvular heart disease evaluation |
| Bilan pre TAVI      | TAVI evaluation                   |

#### • Follow-up after HTX

| FR-Description       | EN-Description                  |
|----------------------|---------------------------------|
| Bilan transplatation | Post transplantation evaluation |

# • Heart failure (LVEF < 40%)

| FR-Description         | EN-Description    |
|------------------------|-------------------|
| Choc cardiogénique     | Cardiogenic shock |
| Insuffisance cardiaque | Heart failure     |

# • Routine follow-up (e.g. after left main PCI)

| FR-Description                              | EN-Description                            |
|---|---|
| Contrôle ATL                                | PCI control                               |
| Coro d'évaluation (FFR, OCT, IVUS contrôle) | Angio assessment (FFR, OCT, IVUS control) |
| Contrôle ATC post-IDM                       | PCI control post-IDM                      |

#### • Tachy- or bradyarrhythmia

|                               | EIN-Description | FR-Description |
|-------------------------------|-----------------|----------------|
| ED-Description EN-Description | EN-Description  | FR-Description |

### Planned vascular surgery

| FR-Description                  | EN-Description           |
|---------------------------------|--------------------------|
| Chirurgie vasculaire programmée | Planned vascular surgery |

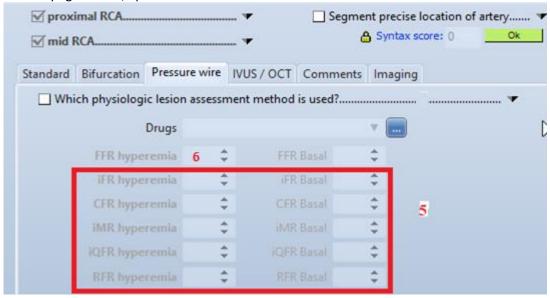
#### • Planned major surgery

| FR-Description                        | EN-Description                         |
|---------------------------------------|--|
| Bilan pré-opératoire non cardiaque    | Pre-operative evaluation               |
| Bilan pré-opératoire cardiovasculaire | Preoperative cardiovascular assessment |
| Bilan pré greffe                      | Pre-transplant evaluation              |

#### IV- Resting index (iFR/RFR) & FFR

If intracoronary physiology is taken it is filled in for each assessed lesion:

Lesions page -> Add/open lesion -> Pressure wire Tab

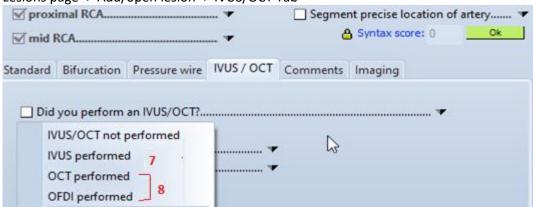


- 5- Resting index (iFR/RFR) = iFR + CFR + iMR + iQFR + RFR > 0
- **6- FFR** = "FFR hyperemia > 0

# **V- IVUS/OCT**

If **intracoronary imaging** is performed it is filled in for each assessed lesion:

Lesions page -> Add/open lesion -> IVUS/OCT Tab



8- OFDI = OCT

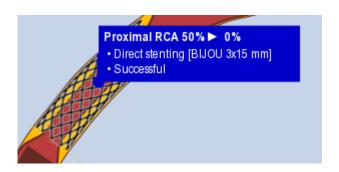
# VI-PCI aborted (V2)

If there are no PCI-result in angioplasty or all PCI-result are failed so the PCI is aborted. This deactivates these questions: no treated lesions/vessels, left main stenosis treated, no stents/balloons, bifurcation, interventions stent failure and calcium modification.

#### VII- Number of treated lesions & vessels

**The Number of treated lesions & vessels** is automatically derived from entries in the Angioplasty page.

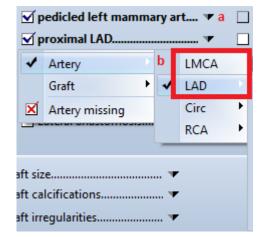
1) Number of treated lesions: All lesions for which a "successful" treatment result has been entered are counted.



- 2) Number of treated vessels: All vessels which have been treated are counted and the total number is transmitted to SwissCaRe. In case of bifurcations only the proximal vessel counts.
- **3)** Unprotected LM stenosis treated is "Yes" when an LM lesion without and LIMA-LAD graft is treated.

A LIMA-LAD graft is defined as:

- a- Graft equal to "pedicled left mammary artery graft" or "free left mammary artery graft"
- b- And artery equal to "LMCA" or "LAD"



# VIII- Number of implanted stents & used drug-eluting balloons

The Number of implanted stents / drug-eluting balloons are derived from entries in the Angioplasty page.

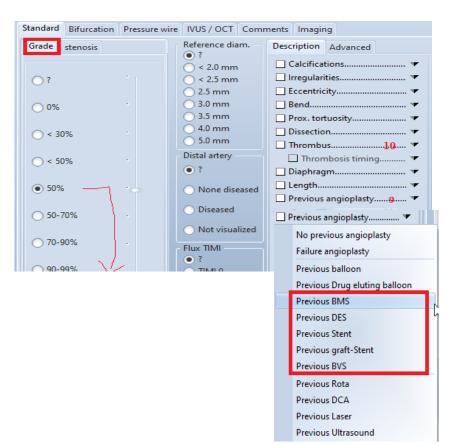
Materials entered in Stent or Balloon treatment must be saved in the correct device categories (Stent & Drug-eluting balloons).



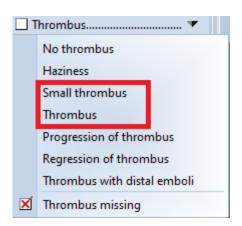
#### IX- Restenosis & Stent Thrombosis

**In case of interventions for Stent Failure** the information in the SwissCaRe form is derived from the Lesions and Angioplasty page.

9- Restenosis is checked when a lesion is treated with "Grade" >= 50% and "Previous angioplasty" is one of the highlighted items (PCI with stent).



**10- Stent thrombosis** is checked when a lesion is treated with "**Grade**" >= 50% and "**Previous angioplasty**" is one of the items above (see Restenosis) and additionally "**Thrombus**" is one of these items:



#### X- CTO procedure

In case of a CTO procedure the information is derived from entries in Lesion and Angioplasty page.

CTO is defined as a lesion with 100% occlusion since at least 3 months. The CTO must be treated as well.

In the SwissCaRe form the access to the CTO is coded as

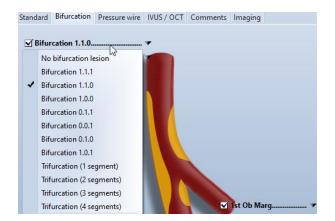
- 1 = Antegrade (default)
- 2 = Retrogade when in the Angioplasty page "guidewire used" = "Retrograde intraluminal"



#### XI- Bifurcation

**If Bifurcating lesions are treated with Stents** the information is automatically derived from the Lesions and Angioplasty pages.

Lesions across a **bifurcation** are automatically recognized in cardioreport or can be manually modified in the Lesion specifications -> bifurcation tab:

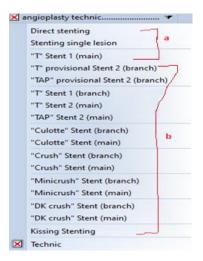


When a lesion over a bifurcation is treated with a stent this is entered in the Angioplasty Page. The stent orientation in the bifurcation is entered in "angioplastic technic" (12):



- **a- 1 stent** is checked when "angioplasty technic" of all stents implanted are in section "a"
- **b- 2 stents** is checked when "angioplasty technic" of all stents implanted are in section "b"

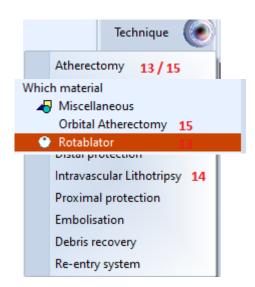
**Note:** If there are several bifurcating lesions treated with both 1 and 2 stents then bifurcation = 2 (stents).



#### XII- Calcium modification (Rotablation, Lithotripsy, Orbital Atherectomy, ...)

The usage of the calcium modifying techniques **Rotablation**, **Lithotripsy and Orbital Atherectomy** are derived from entries in the Angioplasty page -> Technique -> Device category.

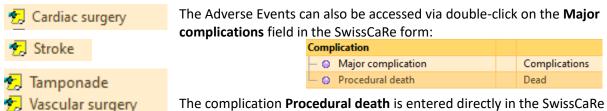
- **13- Rotablation** is checked when the technique "**Atherectomy**" is selected and a device of the type "**Rotablator**" is selected.
- **14- Lithotripsy** is checked when the technique "**Intravascular Lithotripsy**" is selected.
- **15- Orbital atherectomy** is checked when the technique "Atherectomy" is selected and a device of the type "Orbital Atherectomy" is selected.



The usage of the calcium modifying techniques **Cutting balloon**, **Scoring balloon** and **High-pressure balloon** are entered directly in the SwissCaRe form.

#### XIII- Major complications

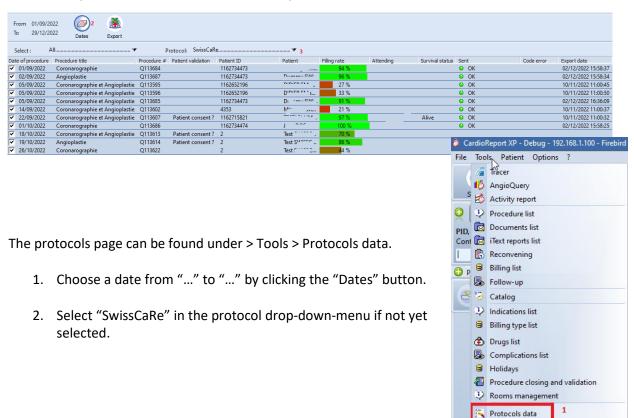
Complications during the procedure are entered in the Tab Adverse Events > Add...



The complication **Procedural death** is entered directly in the SwissCaRe form.

#### XIV- SwissCaRe Protocol

Via the Protocols page the status (completeness, transfer status to SwissCaRe) of the SwissCaRe forms of all patients can be viewed in CardioReport.



#### XV-

#### **Important notes**

- **A**. SwissCare registry is available only for those procedure Types:
  - **1.** Coronary angiography
  - 2. Coronary angiography and PCI
  - 3. Angioplasty «PCI»
- **B**. Some chapters are only visible for certain type of procedure as follows:
  - 1. Baseline Characteristics is visible only for "Coronary angiography and PCI".
  - 2. Indication and Symptoms is **not visible** for "PCI".
  - 3. Treatment is visible only for "Coronary angiography".
  - 4. PCI-specific procedural characteristics is **not visible** for "Coronary angiography".
  - **5.** Medication is **not visible** for "Coronary angiography".
- C. The hospitals that have added other indications in cardioreport specific to them must attach each indication to an indication code to be able to export the data requested by Swisscare correctly.
- **D**. for **complete** data **submission**, you must fill in all the **mandatory fields** and for **Coro-PCI** or **PCI**, you must have at least one **lesion treated** and one **vessel treated** or the **PCI** is **aborted**.