

October 2020
SIS Medical reference: 2010261

Urgent Field Safety Notice
OPN NC® Super High Pressure PTCA Balloon
Updated Rated Burst Pressure (RBP)

Dear Customer,

This notification is to inform you about a change to the Rated Burst Pressure of the OPN NC Super High Pressure PTCA Balloon. As part of our continuous improvement efforts, SIS Medical has increased its internal requirements by applying higher standards for the declaration of the Rated Burst Pressure for the OPN NC balloon. As a result, SIS Medical is voluntarily, with immediate effect, reducing the Rated Burst Pressure for the OPN NC Super High Pressure PTCA balloon from 35 atm to 32 atm.

The most common potential consequence related excessive pressurization is a balloon burst that leads to a prolonged procedure while the device is exchanged. The most severe consequence would be an embolism in a coronary vessel. There have been no patient harms reported to date related to this issue. An overview of the affected devices can be found in table 1 below.

Description	Product Description	Article Number [REF]	Lot Number
OPN NC® Super High Pressure PTCA Balloon	OPN NC Ø1.5-10	150-010-004	All lot numbers
	OPN NC Ø1.5-15	150-015-004	
	OPN NC Ø1.5-20	150-020-004	
	OPN NC Ø2.0-10	200-010-004	
	OPN NC Ø2.0-15	200-015-004	
	OPN NC Ø2.0-20	200-020-004	
	OPN NC Ø2.5-10	250-010-004	
	OPN NC Ø2.5-15	250-015-004	
	OPN NC Ø2.5-20	250-020-004	
	OPN NC Ø3.0-10	300-010-004	
	OPN NC Ø3.0-15	300-015-004	
	OPN NC Ø3.0-20	300-020-004	
	OPN NC Ø3.5-10	350-010-004	
	OPN NC Ø3.5-15	350-015-004	
	OPN NC Ø3.5-20	350-020-004	
	OPN NC Ø4.0-10	400-010-004	
	OPN NC Ø4.0-15	400-015-004	
	OPN NC Ø4.0-20	400-020-004	
	OPN NC Ø4.5-10	450-010-004	
	OPN NC Ø4.5-15	450-015-004	
	OPN NC Ø4.5-20	450-020-004	

Table 1: Overview of affected devices

The OPN NC balloons can be identified in your inventory by the following indication on the device label:



Figure 1: Identification of OPN NC balloons [diameter and balloon length Ø1.5 x 10 are for information only]

As a result of the change in RBP, the Compliance data are updated, see Table 2 for an overview of Compliance data for each balloon diameter at 32 atm.

Nominal Balloon Diameter [mm]	Balloon Diameter at RBP 32 atm [mm]
1.5	1.69
2.0	2.28
2.5	2.83
3.0	3.44
3.5	3.95
4.0	4.54
4.5	4.92

Table 2: Balloon Diameter at RBP 32 atm

Actions to be taken by the user:

1. Use of the OPN NC Super High Pressure PTCA balloon can be continued at 32 atm Rated Burst Pressure
2. Please ensure this notice is passed to any healthcare professional from your organization that needs to be aware
3. Please complete and return the attached notification form to SIS Medical or your local distributor
4. Please complete and return the included Customer reply form

Your Competent Authority has been informed of this Field Safety Notice.

SIS Medical remains committed to patient safety and providing the highest quality products and services. If you have any questions regarding the content of this notification, please contact your SIS Medical representative or customer service at +41 52 245 09 90.

Your sincerely,

Patrick Broeksteeg
Head of QA & RA, SIS Medical AG