Sapphire PTCA Family Summary of Safety and Clinical Performance (SSCP)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of Sapphire PTCA Family. The Sapphire PTCA Family consists of following family members for the SSCP: Sapphire II PRO Coronary Dilatation Catheter, Sapphire II NC Coronary Dilatation Catheter, Sapphire NC 24 Coronary Dilatation Catheter and Sapphire 3 Coronary Dilatation Catheter.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

Manufacturer's reference number for the SSCP: G-10-0484 Rev 02.

1.0 Device identification and general information

1.1 Device trade name

Sapphire II PRO Coronary Dilatation Catheter
Sapphire II NC Coronary Dilatation Catheter
Sapphire 3 Coronary Dilatation Catheter
Sapphire NC 24 Coronary Dilatation Catheter
Note: for the purpose of this document together referred to as: Sapphire PTCA Family

1.2 Manufacturer's name and address

OrbusNeich Medical B.V.
Drs. W. van Royenstraat 5
3871AN Hoevelaken
The Netherlands

1.3 Manufacturer's single registration number (SRN)

NL-MF-000010907

1.4 Basic UDI-DI

Product	Basic UDI-DI
Sapphire II PRO	087178532942158
Sapphire II NC	08717853292915K
Sapphire NC 24	087192449549156
Sapphire 3	08719244955414U

1.5 Medical device nomenclature description / text

Code: C010401020101
Term description in English "PTCA BALLOON DILATION CATHETERS"

1.6 Class of device

Class III

Sapphire PTCA Family are classified as Class III devices according to MDR classification Rule 6 as outlined in Section 5.2, Chapter III of Annex VIII, due to the fact they are surgically invasive devices for transient use in direct contact with the heart.

1.7 Year when the first certificate (CE) was issued covering the device

Sapphire II PRO: February 03, 2015
Sapphire II NC: February 20, 2014
Sapphire NC 24: March 25, 2020
Sapphire 3: March 26, 2020

1.8 NB's name and the NB's single identification number

NB's name: BSI Group The Netherlands B.V.
Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
NB's single identification number: 2797

2.0 Intended use of the device

2.1 Intended purpose

The Sapphire PTCA Family intended for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia.

2.2 Indication and target population

The Sapphire products are indicated for use in the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion.

- Post-stenting dilatation to achieve stent optimization (this indication only applies to Sapphire II NC and Sapphire NC 24)

The Sapphire products are for patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

2.3 Contraindications and/or limitations

The Sapphire PTCA Family are contraindicated for use in the following patient types:

- Patients with an unprotected left main coronary artery;
- Patients with coronary artery spasm in the absence of a significant stenosis.

3.0 Device description

3.1 Description of the device

The OrbusNeich Sapphire PTCA Family is designed to allow easy exchange of the catheter using a standard-length guidewire. Balloon diameters range from 0.85 mm to 5.0 mm. The balloon material is made of Pebax/nylon material. The proximal shaft of the catheter is composed of a female luer connector bonded to a jacketed stainless-steel tube assembly. The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube of Pebax/nylon and a tri-extrusion inner tube with a balloon laser welded to both tubes at the distal tip. Two radiopaque platinum/iridium marker bands

are located within the balloon segment with the balloon diameters 2.0 mm to 5.0 mm. A single-marker band is centrally positioned within the balloon segment with balloon diameter 0.85 mm to 1.5 mm, while the 1.75 mm diameter balloon incorporates both configurations, with 2 marker bands and 1 central marker band. The inner tube accepts a standard 0.014 inch PTCA guidewire. The guidewire enters the catheter's tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard-length guidewire. Two marked sections located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of these dilatation catheters does not incorporate a lumen for distal dye injections or distal pressure measurements.

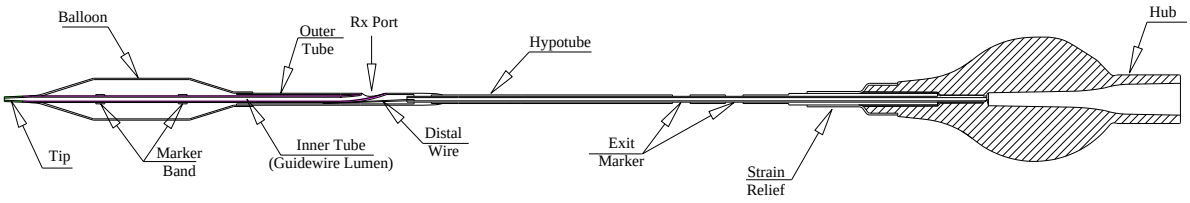
The devices are sterilized with ethylene oxide and are intended for single-use only.

The Sapphire PTCA Family incorporate a hydrophilic coating, other materials adopted including:

- Balloon: Pebax/nylon
- Distal outer body: Pebax/nylon
- Tip tubing: Pebax
- Proximal shaft: jacketed 304 stainless steel / Pebax/nylon
- Marker band is platinum/iridium
- Other materials: polyethylene and Lexan

The device components include a catheter with tip and dilatable balloon portion attached to a hub via the hypotube external to the patient. The catheter is cannulated, allowing separate guidewire to pass through. Mechanical characteristics include flexibility to improve navigation and semi-compliant/minimal-compliant balloon to allow for controlled expansion. Figure 1 is an image that represents all Sapphire PTCA Family models.

Figure 1 Image of Coronary Dilatation Catheter from Sapphire PTCA Family



Key functional elements and materials in contact with the patient tissues

The Sapphire PTCA Family key functional elements and materials in contact with the patient tissues listed as the following table 1-1 to table 1-4 respectively:

Table 1-1, Sapphire II PRO key elements in contact with the patient tissue

Key functional elements	Materials in contact with the patient's tissue
Tip	Pebax
Balloon	Nylon/Pebax
Distal Shaft	HDPE/LLDPE/Nylon/Pebax
Hypotube with Distal Wire	PTFE coated Stainless Steel
Coating	Hydrophilic coating/Silicone coating

Table 1-2, Sapphire II NC key elements in contact with the patient tissue

Key functional elements	Materials in contact with the patient's tissue
Tip	Pebax/Plexar/ HDPE
Balloon	Nylon
Distal Shaft	HDPE/LDPE/Nylon
Hypotube with Distal Wire	PTFE coated Stainless Steel
Coating	Hydrophilic coating/Silicone coating

Table 1-3, Sapphire NC 24 key elements in contact with the patient tissue

Key functional elements	Materials in contact with the patient's tissue
Tip	Pebax
Balloon	Pebax/Nylon
Distal Shaft	HDPE/LLDPE/Nylon/Pebax
Proximal Shaft	PTFE coated Stainless Steel
Coating	Hydrophilic coating/Silicone coating

Table 1-4, Sapphire 3 key elements in contact with the patient tissue

Key functional elements	Materials in contact with the patient's tissue
Tip	Pebax
Balloon	Nylon/Pebax
Distal Shaft	HDPE/LLDPE/Nylon/Pebax
Proximal Shaft	PTFE coated Stainless Steel
Coating	Hydrophilic coating/Silicone coating

List and description of any variants and/or configurations

The Sapphire PTCA Family nominal balloon diameters range from 0.85mm – 5.00 mm. Balloon lengths range from 5mm – 30 mm. The currently MDD CE approved balloon sizes of each of the family member is represented in Table 2 to Table 5:

Table 2, Sapphire II PRO Catalog Codes

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
210-053-5U	1.0 mm x 5 mm	6atm	16atm
210-083-5U	1.0 mm x 8 mm	6atm	16atm
210-103-5U	1.0 mm x 10 mm	6atm	16atm
210-153-5U	1.0 mm x 15 mm	6atm	16atm
212-053-5U	1.25 mm x 5 mm	6atm	16atm
212-083-5U	1.25 mm x 8 mm	6atm	16atm
212-103-5U	1.25 mm x 10 mm	6atm	16atm
212-153-5U	1.25 mm x 15 mm	6atm	16atm
215-103-5U	1.5 mm x 10 mm	6atm	16atm
215-123-5U	1.5 mm x 12 mm	6atm	16atm
215-153-5U	1.5 mm x 15 mm	6atm	16atm
215-203-5U	1.5 mm x 20 mm	6atm	16atm
217-103-5U	1.75 mm x 10 mm	6atm	14atm
217-153-5U	1.75 mm x 15 mm	6atm	14atm
217-203-5U	1.75 mm x 20 mm	6atm	14atm
220-103-5U	2.0 mm x 10 mm	6atm	14atm
220-123-5U	2.0 mm x 12 mm	6atm	14atm
220-153-5U	2.0 mm x 15mm	6atm	14atm
220-203-5U	2.0 mm x 20 mm	6atm	14atm
222-103-5U	2.25 mm x 10 mm	6atm	14atm
222-153-5U	2.25 mm x 15 mm	6atm	14atm
222-203-5U	2.25 mm x 20 mm	6atm	14atm
225-103-5U	2.5 mm x 10 mm	6atm	14atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
225-123-5U	2.5 mm x 12 mm	6atm	14atm
225-153-5U	2.5 mm x 15 mm	6atm	14atm
225-203-5U	2.5 mm x 20 mm	6atm	14atm
225-303-5U	2.5 mm x 30 mm	6atm	14atm
227-103-5U	2.75 mm x 10 mm	6atm	14atm
227-153-5U	2.75 mm x 15 mm	6atm	14atm
227-203-5U	2.75 mm x 20 mm	6atm	14atm
230-103-5U	3.0 mm x 10 mm	6atm	14atm
230-123-5U	3.0 mm x 12 mm	6atm	14atm
230-153-5U	3.0 mm x 15 mm	6atm	14atm
230-203-5U	3.0 mm x 20 mm	6atm	14atm
230-303-5U	3.0 mm x 30 mm	6atm	14atm
232-103-5U	3.25 mm x 10 mm	6atm	14atm
232-153-5U	3.25 mm x 15 mm	6atm	14atm
232-203-5U	3.25 mm x 20 mm	6atm	14atm
235-103-5U	3.5 mm x 10 mm	6atm	14atm
235-153-5U	3.5 mm x 15 mm	6atm	14atm
235-203-5U	3.5 mm x 20 mm	6atm	14atm
235-303-5U	3.5 mm x 30 mm	6atm	14atm
240-103-5U	4.0 mm x 10 mm	6atm	14atm
240-153-5U	4.0 mm x 15 mm	6atm	14atm
240-203-5U	4.0 mm x 20 mm	6atm	14atm

Table 3, Sapphire II NC Catalog Codes

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
117-1708	1.75 x 8 mm	12 atm	20 atm
117-1710	1.75 x 10 mm	12 atm	20 atm
117-1712	1.75 x 12 mm	12 atm	20 atm
117-1715	1.75 x 15 mm	12 atm	20 atm
117-1718	1.75 x 18 mm	12 atm	20 atm
117- 2008	2.0 x 8 mm	12 atm	20 atm
117-2010	2.0 x 10 mm	12 atm	20 atm
117-2012	2.0 x 12 mm	12 atm	20 atm
117-2015	2.0 x 15 mm	12 atm	20 atm
117-2018	2.0 x 18 mm	12 atm	20 atm
117- 2208	2.25 x 8 mm	12 atm	20 atm
117-2210	2.25 x10 mm	12 atm	20 atm
117-2212	2.25 x 12 mm	12 atm	20 atm
117-2215	2.25 x 15 mm	12 atm	20 atm
117-2218	2.25 x 18 mm	12 atm	20 atm
117- 2508	2.5 x 8 mm	12 atm	20 atm
117-2510	2.5 x 10 mm	12 atm	20 atm
117-2512	2.5 x 12 mm	12 atm	20 atm
117-2515	2.5 x 15 mm	12 atm	20 atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
117-2518	2. 5 x 18 mm	12 atm	20 atm
117- 2708	2.75 x 8 mm	12 atm	20 atm
117-2710	2.75 x 10 mm	12 atm	20 atm
117-2712	2.75 x 12 mm	12 atm	20 atm
117-2715	2.75 x 15 mm	12 atm	20 atm
117-2718	2.75 x 18 mm	12 atm	20 atm
117-3008	3.0 x 8mm	12 atm	20 atm
117-3010	3.0 x 10mm	12 atm	20 atm
117-3012	3.0 x 12mm	12 atm	20 atm
117-3015	3.0 x 15mm	12 atm	20 atm
117-3018	3.0 x 18mm	12 atm	20 atm
117- 3208	3.25 x 8 mm	12 atm	20 atm
117-3210	3.25 x 10 mm	12 atm	20 atm
117-3212	3.25 x 12 mm	12 atm	20 atm
117-3215	3.25 x 15 mm	12 atm	20 atm
117-3218	3.25 x 18 mm	12 atm	20 atm
117-3508	3.5 x 8 mm	12 atm	20 atm
117-3510	3.5 x 10 mm	12 atm	20 atm
117-3512	3.5 x 12 mm	12 atm	20 atm
117-3515	3.5 x 15 mm	12 atm	20 atm
117-3518	3.5 x 18 mm	12 atm	20 atm
117-3708	3.75 x 8 mm	12 atm	20 atm
117-3710	3.75 x 10 mm	12 atm	20 atm
117-3712	3.75 x 12 mm	12 atm	20 atm
117-3715	3.75 x 15 mm	12 atm	20 atm
117-3718	3.75 x 18 mm	12 atm	20 atm
117-4008	4.0 x 8 mm	12 atm	20 atm
117-4010	4.0 x 10 mm	12 atm	20 atm
117-4012	4.0 x 12 mm	12 atm	20 atm
117-4015	4.0 x 15 mm	12 atm	20 atm
117-4018	4.0 x 18 mm	12 atm	20 atm
117- 4508	4.5 x 8 mm	12 atm	18 atm
117-4510	4.5 x 10 mm	12 atm	18 atm
117-4512	4.5 x 12 mm	12 atm	18 atm
117-4515	4.5 x 15 mm	12 atm	18 atm
117-4518	4.5 x 18 mm	12 atm	18 atm
117-5008	5.0 x 8 mm	12 atm	18 atm
117-5010	5.0 x 10 mm	12 atm	18 atm
117-5012	5.0 x 12 mm	12 atm	18 atm
117-5015	5.0 x 15 mm	12 atm	18 atm
117-5018	5.0 x 18 mm	12 atm	18 atm

Table 4, Sapphire NC 24 Catalog Codes

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
215-084-5	1.5x8mm	14atm	24atm
215-104-5	1.5x10mm	14atm	24atm
215-124-5	1.5x12mm	14atm	24atm
215-154-5	1.5x15mm	14atm	24atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
215-184-5	1.5x18mm	14atm	24atm
215-224-5	1.5x22mm	14atm	24atm
215-264-5	1.5x26mm	14atm	24atm
217-084-5	1.75x8mm	14atm	24atm
217-104-5	1.75x10mm	14atm	24atm
217-124-5	1.75x12mm	14atm	24atm
217-154-5	1.75x15mm	14atm	24atm
217-184-5	1.75x18mm	14atm	24atm
217-224-5	1.75x22mm	14atm	24atm
217-264-5	1.75x26mm	14atm	24atm
220-084-5	2.0x8mm	14atm	24atm
220-104-5	2.0x10mm	14atm	24atm
220-124-5	2.0x12mm	14atm	24atm
220-154-5	2.0x15mm	14atm	24atm
220-184-5	2.0x18mm	14atm	24atm
220-224-5	2.0x22mm	14atm	24atm
220-264-5	2.0x26mm	14atm	24atm
222-084-5	2.25x8mm	14atm	24atm
222-104-5	2.25x10mm	14atm	24atm
222-124-5	2.25x12mm	14atm	24atm
222-154-5	2.25x15mm	14atm	24atm
222-184-5	2.25x18mm	14atm	24atm
222-224-5	2.25x22mm	14atm	24atm
222-264-5	2.25x26mm	14atm	24atm
225-084-5	2.5x8mm	14atm	24atm
225-104-5	2.5x10mm	14atm	24atm
225-124-5	2.5x12mm	14atm	24atm
225-154-5	2.5x15mm	14atm	24atm
225-184-5	2.5x18mm	14atm	24atm
225-224-5	2.5x22mm	14atm	24atm
225-264-5	2.5x26mm	14atm	24atm
227-084-5	2.75x8mm	14atm	24atm
227-104-5	2.75x10mm	14atm	24atm
227-124-5	2.75x12mm	14atm	24atm
227-154-5	2.75x15mm	14atm	24atm
227-184-5	2.75x18mm	14atm	24atm
227-224-5	2.75x22mm	14atm	24atm
227-264-5	2.75x26mm	14atm	24atm
228-084-5	2.875x8mm	14atm	24atm
228-104-5	2.875x10mm	14atm	24atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
228-124-5	2.875x12mm	14atm	24atm
228-154-5	2.875x15mm	14atm	24atm
228-184-5	2.875x18mm	14atm	24atm
228-224-5	2.875x22mm	14atm	24atm
228-264-5	2.875x26mm	14atm	24atm
230-084-5	3.0x8mm	14atm	24atm
230-104-5	3.0x10mm	14atm	24atm
230-124-5	3.0x12mm	14atm	24atm
230-154-5	3.0x15mm	14atm	24atm
230-184-5	3.0x18mm	14atm	24atm
230-224-5	3.0x22mm	14atm	24atm
230-264-5	3.0x26mm	14atm	24atm
232-084-5	3.25x8mm	14atm	24atm
232-104-5	3.25x10mm	14atm	24atm
232-124-5	3.25x12mm	14atm	24atm
232-154-5	3.25x15mm	14atm	24atm
232-184-5	3.25x18mm	14atm	24atm
232-224-5	3.25x22mm	14atm	24atm
232-264-5	3.25x26mm	14atm	24atm
235-084-5	3.5x8mm	14atm	24atm
235-104-5	3.5x10mm	14atm	24atm
235-124-5	3.5x12mm	14atm	24atm
235-154-5	3.5x15mm	14atm	24atm
235-184-5	3.5x18mm	14atm	24atm
235-224-5	3.5x22mm	14atm	24atm
235-264-5	3.5x26mm	14atm	24atm
237-084-5	3.75x8mm	14atm	22atm
237-104-5	3.75x10mm	14atm	22atm
237-124-5	3.75x12mm	14atm	22atm
237-154-5	3.75x15mm	14atm	22atm
237-184-5	3.75x18mm	14atm	22atm
237-224-5	3.75x22mm	14atm	22atm
237-264-5	3.75x26mm	14atm	22atm
240-084-5	4.0x8mm	14atm	22atm
240-104-5	4.0x10mm	14atm	22atm
240-124-5	4.0x12mm	14atm	22atm
240-154-5	4.0x15mm	14atm	22atm
240-184-5	4.0x18mm	14atm	22atm
240-224-5	4.0x22mm	14atm	22atm
240-264-5	4.0x26mm	14atm	22atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
245-084-5	4.5x8mm	14atm	20atm
245-104-5	4.5x10mm	14atm	20atm
245-124-5	4.5x12mm	14atm	20atm
245-154-5	4.5x15mm	14atm	20atm
245-184-5	4.5x18mm	14atm	20atm
245-224-5	4.5x22mm	14atm	20atm
245-264-5	4.5x26mm	14atm	20atm
250-084-5	5.0x8mm	14atm	20atm
250-104-5	5.0x10mm	14atm	20atm
250-124-5	5.0x12mm	14atm	20atm
250-154-5	5.0x15mm	14atm	20atm
250-184-5	5.0x18mm	14atm	20atm
250-224-5	5.0x22mm	14atm	20atm
250-264-5	5.0x26mm	14atm	20atm

Table 5, Sapphire 3 Catalog Codes

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
208-053-6	0.85 mm x 5 mm	6atm	16atm
208-103-6	0.85 mm x 10 mm	6atm	16atm
210-053-6	1.0 mm x 5 mm	6atm	16atm
210-083-6	1.0 mm x 8 mm	6atm	16atm
210-103-6	1.0 mm x 10 mm	6atm	16atm
210-153-6	1.0 mm x 15 mm	6atm	16atm
212-053-6	1.25 mm x 5 mm	6atm	16atm
212-083-6	1.25 mm x 8 mm	6atm	16atm
212-103-6	1.25 mm x 10 mm	6atm	16atm
212-153-6	1.25 mm x 15 mm	6atm	16atm
215-103-6	1.5 mm x 10 mm	6atm	16atm
215-123-6	1.5 mm x 12 mm	6atm	16atm
215-153-6	1.5 mm x 15 mm	6atm	16atm
215-203-6	1.5 mm x 20 mm	6atm	16atm
217-103-6	1.75 mm x 10 mm	6atm	14atm
217-153-6	1.75 mm x 15 mm	6atm	14atm
217-203-6	1.75 mm x 20 mm	6atm	14atm
220-103-6	2.0 mm x 10 mm	6atm	14atm
220-123-6	2.0 mm x 12 mm	6atm	14atm
220-153-6	2.0 mm x 15mm	6atm	14atm
220-203-6	2.0 mm x 20 mm	6atm	14atm
222-103-6	2.25 mm x 10 mm	6atm	14atm

Catalog	Balloon Size	Nominal Pressure	Target Rated Burst Pressure
222-153-6	2.25 mm x 15 mm	6atm	14atm
222-203-6	2.25 mm x 20 mm	6atm	14atm
225-103-6	2.5 mm x 10 mm	6atm	14atm
225-123-6	2.5 mm x 12 mm	6atm	14atm
225-153-6	2.5 mm x 15 mm	6atm	14atm
225-203-6	2.5 mm x 20 mm	6atm	14atm
225-303-6	2.5 mm x 30 mm	6atm	14atm
227-103-6	2.75 mm x 10 mm	6atm	14atm
227-153-6	2.75 mm x 15 mm	6atm	14atm
227-203-6	2.75 mm x 20 mm	6atm	14atm
230-103-6	3.0 mm x 10 mm	6atm	14atm
230-123-6	3.0 mm x 12 mm	6atm	14atm
230-153-6	3.0 mm x 15 mm	6atm	14atm
230-203-6	3.0 mm x 20 mm	6atm	14atm
230-303-6	3.0 mm x 30 mm	6atm	14atm
232-103-6	3.25 mm x 10 mm	6atm	14atm
232-153-6	3.25 mm x 15 mm	6atm	14atm
232-203-6	3.25 mm x 20 mm	6atm	14atm
235-103-6	3.5 mm x 10 mm	6atm	14atm
235-153-6	3.5 mm x 15 mm	6atm	14atm
235-203-6	3.5 mm x 20 mm	6atm	14atm
235-303-6	3.5 mm x 30 mm	6atm	14atm
240-103-6	4.0 mm x 10 mm	6atm	14atm
240-153-6	4.0 mm x 15 mm	6atm	14atm
240-203-6	4.0 mm x 20 mm	6atm	14atm

Operation principle and mode of action

The Sapphire PTCA Family is designed to treat coronary artery disease with balloon angioplasty. The guidewire is threaded through the narrowing of the occlusion, and then a balloon catheter is guided along the guidewire. Balloon catheters are available in various lengths, so that they can span the entire occluded region. Once in place, a balloon of appropriate diameter is inflated to several atmospheres of pressure to dilate the artery and allow blood to flow. The catheter will be removed and discarded after use.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

All generations of OrbusNeich Sapphire PTCA products have been CE certified under MDD listed in Table 6.

Table 6, Sapphire PTCA Generations

Product Name	CE Certificated	Justifications
Sapphire NC	Yes	Launched in 2008. Available in market. 1st generation, semi-compliant balloon
Sapphire II	Yes	Launched in 2010. Available in market. 1st generation; non-compliant balloon
Sapphire II NC	Yes	Launched in 2014. Available in market.

Product Name	CE Certificated	Justifications
Sapphire II PRO	Yes	Launched in 2015. Available in market.
Sapphire NC 24	Yes	Launched in 2020. Available in market.
Sapphire 3	Yes	Launched in 2020. Available in market.

3.3 Description of any accessories which are intended to be used in combination with the device

Below accessories are supplied with Sapphire PTCA family:

- Re-wrap tool
- Securement clip
- Flushing needle (only supplied for Sapphire II NC and Sapphire II PRO)

Re-wrap tool and Securement clip are provided and fastened in the compliance card, while the Flushing needle is attached in the hoop dispenser. All the accessories are packaged with the device.

The re-wrap tool is a tube in short length of approximately 5 cm, it is used to refold balloon by loading over the deflated balloon post expansion to tighten the loosen balloon, which help catheter to re-entry into the target lesion easier when physicians re-introduce the catheter to a specific lesion of the same patient during a single operation.

The securement clip is used to secure the hypotube segment of the catheter. After completed the PTCA surgery, physicians may discard the catheter or keep it properly stowed in the saline tray for re-insertion by coiling the catheter into a loop and securing the hypotube segment of the catheter with the securement clip.

The flushing needle is used to provide flushing passage to guide wire lumen. In the preparation for catheter use, attach a syringe filled with heparinized normal saline to a flushing needle, gently insert the needle into the tip of the catheter and flush the guidewire lumen with heparinized normal saline until fluid is seen exiting the guidewire port.

3.4 Description of any other devices and products which are intended to be used in combination with the device

RECOMMENDED ADDITIONAL MATERIALS FOR SAPPHIRE PTCA FAMILY

- Arterial sheath
- Femoral or brachial guiding catheter in the appropriate size and configuration (diameter not to be less than the minimum recommended guide diameter; see product label)
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- 20cc Luer-lock syringe
- Flushing needle
- Inflation device
- Guidewire diameter not to exceed 0.014"; see product label
- Guidewire introducer
- Guidewire torque device

4.0 Risks and warnings

4.1 Residual risks and undesirable effects

All residual risks are assessed and documented in the risk management files of Sapphire PTCA Family according to ISO 14971 standard. The overall residual risk posed by Sapphire PTCA Family is judged acceptable using the criteria defined in the Failure Mode Effects Analysis and the medical benefits of

the intended use to the patient outweigh the residual risk. The Instruction For Use disclosed the residual risks and undesirable effects associated with the patient and clinician.

The undesirable effects as the following

Potential complications and adverse effects due to the use of this product include, but are not limited to, the following:

- Death
- Acute myocardial infarction
- Acute vessel closure
- Aneurysm
- Total occlusion of the coronary artery or bypass graft
- Coronary vessel dissection, perforation, rupture or injury
- Restenosis of the dilated vessel
- Hemorrhage or hematoma
- Unstable angina
- Arrhythmias, including ventricular fibrillation
- Drug reactions, allergic reaction to contrast medium
- Hypo/hypertension
- Infection
- Coronary artery spasm
- Arteriovenous fistula
- Embolism
- Balloon burst due to lesion characteristics

This is a qualitative assessment (estimate) of the incidents occurrence rate. The assessment was performed based on the data collected from complaints and incidents. “Complaints” means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability reliability, safety, effectiveness, or performance of a medical device; While ″Incidents” means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

All complaints and incidents rate from 1 May 2022 to the end of November 2023 was summarized as below Table 7.

Table 7, Sapphire PTCA Family Complaints and incidents Rate Summary

Product	Global Market		EU Market	
	Complaint Rate	Incident Rate	Complaint Rate	Incident Rate
Sapphire PTCA family (Sapphire II PRO, Sapphire II NC, Sapphire NC 24 & Sapphire 3)	0.0186%	0.0017%	0.0083%	0.0023%
	0.0084%	0.0009%	0.0062%	0.0004%

The complaints by category in global and EU market were summarized and analyzed.

Based on the review of the Medical Device Vigilance incident report, there is no evidence of systemic product malfunctions, inadequacy in the IFU or manufacturing defects.

OrbusNeich conducts annual risk management review meeting to review regulations and standards, current knowledge/ state of the art, competitive products MDV/MDR, customer complaints and non-conforming material report. The review of competitive PTCA product MDR data from MAUDE database revealed similar types of complaints and incidents. The most common incidents are the balloon not holding pressure. For all balloon catheter products, this was the dominant malfunction. In

other instances, shaft related events such as kinking, break, fracture and leak occurred. There is no unexpected risk identified from the vigilance data.

The potential complications and incidents of the Sapphire PTCA Family are acceptable when weighed against the benefit to the patient. The potential incidents are common to the practice of PCI (not the particular brand/model of balloon catheter). Additionally, patients requiring a PCI typically present with co-morbidities that are already present in the incidents listing (i.e. hypertension is also a predictor of coronary artery disease).

In the Instructions for Use (IFU) of OrbusNeich Sapphire PTCA Family balloon dilatation catheters, potential complications and incidents are consistent with the clinical data, competitive product instructions for use as well as search results from the MAUDE database. Furthermore, our latest risk management review has been performed in April 2022, all the current products and its corresponding risk management documents had been reviewed (including Sapphire PTCA Family). Taking into account the most recent data from the PMS, OrbusNeich concluded that the medical benefits outweighed the residual risk. The overall residual risk was considered acceptable in relation to the benefits of the intended use. Therefore, based upon the benefit to the patient (treatment of coronary artery disease) and no new risks for Sapphire PTCA Family compared to other commercially-available devices, the potential side-effects of the Sapphire PTCA Family balloon dilatation catheters are determined to be acceptable.

4.2 Warnings and precautions

WARNINGS

When using this type of device, the following warnings should be observed, failure to abide by the warnings in this labelling might result in damage to the device, which ma necessitate intervention or result in serious adverse events.

- Do not use if the package is damaged or opened.
- Do not use or attempt to straighten a catheter if the shaft has become bent or kinked, this may result in the shaft breaking.
- Use the catheter prior to the “Use By” date specified on the package.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- This device is designed and intended for single use only. DO NOT reprocess, resterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Reuse may lead to impairment of functional performance. Infections and/or limited performance of the device may lead to injury, illness or death of the patient.
- Persons with known history of allergies to any of the components of this device listed below may suffer an allergic reaction to this coronary dilation catheter. Prior its use on the patient, the patient should be counseled on the materials contained in the device, and a thorough history of allergies must be discussed. This device contains: polyvinyl pyrrolidone coating, polyamide, polyether block amide (PEBAX), and polyethylene.
- Do not re-straighten a kinked hypotube; straightening a kinked metal shaft may result in breakage of the shaft.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The RBP is based on results of in vitro testing. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. If gaseous medium is used and balloon rupture, there is a potential of causing air embolism and/or vessel injury.
- Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with increase in the risk acute closure, vessel trauma, balloon burst, balloon entrapment, and associated complications.
- The outside diameter of the distal 32 cm of the device, including the distal shaft and tip are coated with hydrophilic coating. Avoid wiping the device with dry gauze, or using alcohol antiseptic solutions, or other solvents to pre-treat the device, as this may impact the coating performance.

PRECAUTIONS

- Do not reinsert the PTCA catheter into the coil dispenser after procedural use.
- To confirm sterility has been maintained, ensure that the package sterile barrier has not been opened or damaged prior to use.
- Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is being used.
- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician.
- If the surface of the coronary dilation catheter becomes dry, wet with heparinized normal saline to reactivate the coating.
- The design and construction of these catheters do not provide the user with distal pressure monitoring capability.
- Discard all disposable devices used during the procedure per local requirements for medical device waste disposal.
- Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage, or lubrication loss.
- The safety and performance of these devices have not been established, or is unknown, in vascular regions other than those specifically indicated.
- The safety and performance of these devices has not been established in the pediatric population.
- Use with caution for procedures involving calcified lesions due to the abrasive nature of these lesions.
- The safety and performance of this device in the use of post-stent dilation have not been established. This device has not been validated for post stent dilatation for the optimization of the stent deployment (this precaution only applies to Sapphire II PRO and Sapphire 3).

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

There is no field safety corrective action reported on Sapphire PTCA Family since its first launch on the EU market.

5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device

All devices of OrbusNeich Sapphire PTCA products are claimed to be equivalent devices. Sapphire II PRO, Sapphire II NC, Sapphire NC 24 and Sapphire 3 are covered in this SSCP.

The technology supporting the Sapphire catheters is based on well-established safety and performance characteristics. The current design concepts and technologies were inherited from predecessor products. Changes in dilation balloon catheters over the past 10 years are minor refinements, and the core technology remains within SOA.

The Sapphire catheter models are identical in many respects, but are manufactured to different specifications in other respects, such as balloon sizes and pressures, to allow for selection based on an individual need. Regarding pressure-resistance, because the different Sapphire catheter models have the same intended action, the balloons are pressurized to compress the atherosclerosis or lesion and expand the vessel wall, the nominal pressure is only a way to achieve the target vessel diameter, and the selection of the balloon diameter is based on the expertise of the trained physicians.

The Sapphire portfolio of coronary dilation balloon catheters is designed to treat coronary artery disease with balloon angioplasty. The expected patient population presents with coronary ischemia due to a stenosis of the coronary artery and the goal of treatment is improvement in myocardial perfusion. The different Sapphire portfolio catheter models are identical in many respects, but are manufactured to different specifications in other respects, such as balloon sizes and pressures, to allow for selection on the basis of an individual patient's need.

Regarding pressure-resistance, because the different Sapphire portfolio catheter models have the same intended action, the balloons are pressurized to compress the atherosclerosis or lesion and expand the vessel wall, the nominal pressure is only a way to achieve the target vessel diameter, and the selection of the balloon diameter is based on the expertise of the trained cardiologist.

Regardless of the nominal pressure differences, the balloon diameter at nominal pressure will be the same for a fixed balloon configuration, e.g., balloon of 2.0 mm diameter. The rated burst pressure (RBP) (i.e., statistical measure indicating that 99.9% of the balloons will not burst at or below this pressure, with 95% confidence) ranges from 14 to 22 atm across Sapphire device models. The treatment goal is achieved by physical action, regardless of whether a non-compliant balloon (high pressure) or semi-compliant balloon (mid-pressure) is used, and all device model materials and all applications of the various device models are similar, if not identical.

Although the detailed material codes are varied, Sapphire portfolio are considered substantially equivalent from the material science perspective; and they all have been widely and commonly used in the industry and successfully validated in biocompatibility testing respectively.

OrbusNeich conducted product registration trials of devices within the Sapphire family in conformity with the appropriate good clinical practice [GCP] and ethical standards. In order to support product registration, OrbusNeich conducted two clinical trials of Sapphire II and Sapphire II NC products in China comparing with Sapphire and Sapphire NC respectively, and one clinical trial of the Sapphire II PRO was conducted in the United States. Summaries of the three clinical trials are provided below and full clinical trial reports are provided. The design and execution of the trials conducted in China were based on China Food and Drug Administration (CFDA) Medical Device Clinical Trial Regulations (Directive No. 5). China CFDA Directive No. 5 conforms to World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects and International

Conference on Harmonisation (ICH) / WHO Good GCP standards. Likewise, the Sapphire II PRO clinical trial was conducted in conformity with ISO 14155 Good Clinical Practices (ref 8.8) and the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects and International Conference on Harmonisation (ICH) / WHO Good GCP standards.

Results of the three clinical studies showed a combined population of 341 subjects who had balloon angioplasty with one of the Sapphire portfolio of devices had nearly 100% procedural success with no device related adverse events. A similarly high rate of success was observed for effectiveness and safety endpoints related to technical aspects of catheter use and absence of procedural complications. PCI is conducted according to standard procedures around the world without reported evidence of differences in procedural success among patient populations in different regions.

(1) Sapphire II Clinical Trial

Period: 24 June 2011 to 30 November 2011
Report Date: 30 March 2012
Clinical trial sites (China): Capital Medical University Affiliated Beijing Chao-Yang Hospital and Daqing Oilfield General Hospital

This prospective, randomized, multicenter, parallel, controlled study was designed to verify the safety and effectiveness of the Sapphire II single-use coronary balloon catheter. The study compared the Sapphire II model device with the predecessor Sapphire model device. The study enrolled subjects with coronary artery disease requiring balloon dilation. Potential subjects with unprotected left main diseases; coronary spasm with no significant stenosis; or serious calcification lesion, angulated lesion or other lesions impossible or difficult to pass through were excluded from the study.

(2) Sapphire II NC Clinical Trial

Period: 08 May 2013 to 16 May 2014
Report Date: 20 May 2014
Clinical trial sites (China): Daqing Oilfield General Hospital and Chinese People's Liberation Army No. 254 Hospital

This prospective, randomized, multicenter, parallel, controlled study was designed to verify the safety and effectiveness of the Sapphire II NC single-use coronary balloon catheter. The study compared the Sapphire II NC model device with the Sapphire NC model device. The study enrolled subjects with coronary artery disease requiring balloon dilation. Potential subjects with unprotected left main diseases; coronary spasm with no significant stenosis; or serious calcification lesion, angulated lesion or other lesions impossible or difficult to pass through were excluded from the study.

(3) Sapphire II PRO Clinical Trial [NCT03052530]

Period: 10 May 2017 to 24 July 2017
Report Date: 01 February 2018
Clinical trial sites (United States): Piedmont Heart Institute (Atlanta, GA); The Christ Hospital Heart and Vascular (Cincinnati, OH); Peninsula Regional Medical Center (Salisbury, MD); University of Miami (Miami, FL)

This prospective, open-label, multi-center, single-arm, observational study was designed to evaluate the acute safety and device procedural success of the Sapphire II PRO 1.0mm and 1.25 mm coronary

dilatation catheter in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention (>70% diameter stenosis).

Summation of 3 clinical trials Results for Sapphire PTCA Family
Based on the results of the performance and safety endpoints of the 3 investigations, the prospectively defined measurable objectives of the study protocols were met.

5.2 Summary of clinical data from conducted investigations of the device before CE-marking

The Clinical investigation of Sapphire II NC and Sapphire II PRO were summarized in Section 5.1 as above.

5.3 Summary of clinical data from other sources

(1) 2023 Annual Physician product evaluation for entire Sapphire PTCA Family

Annual physician survey was conducted and collected from September 2022 to September 2023 for Sapphire PTCA Family. A total of 159 units of products were evaluated by 58 physicians at 43 hospitals across 6 countries (Germany, France, Switzerland, Spain, Iran and Saudi Arabia).

Based on the analysis of the feedback on 159 device usages regarding the clinical safety and performance of Sapphire PTCA Family, it can be concluded that the product family is safe and performs adequately in accordance with user expectations. Furthermore, Sapphire PTCA Family performed well in comparison with physician experience with competitive devices, as demonstrated by the positive ratings and the collected comments.

(2) Six-Month Post-production Monitoring

Post-production monitoring for each member of Sapphire PTCA Family was conducted per the post-market surveillance plan of each member respectively.

Sapphire II PRO Post-production Monitoring

The Sapphire II PRO received CE mark approval on Feb 03, 2015. The methods for gathering the clinical experience were followed for Sapphire II PRO per P140071 Sapphire II PRO Post-Market Surveillance Plan.

Data is collected from the following sources:

- Sales Meeting and Product Training Sessions
- Physician Surveys

The sales training meetings were completed and a total of twenty (20) surveys from Japan were filled out after the sales conference by members of the direct sales forces. The overall performance of the Sapphire II PRO in region was rated versus their market leader(s).
During the nine-month clinical usage interval (January to October 2015), one hundred and sixty-six (166) surveys were evaluated by one hundred and one (101) physicians at sixty-five (65) hospitals were collected and analyzed with regards the predetermined clinical performance of the Sapphire II PRO product. Based on the feedback collected, the overall assessment for Sapphire II PRO was positive and competitive against the leading product on the market, and the clinical performance of the Sapphire II PRO has met the users' needs.

Sapphire II NC Post-production Monitoring

The Sapphire II NC received CE mark approval on February 20, 2014. The methods for gathering the clinical experience were followed for Sapphire II PRO per P130016 Sapphire II NC Post Production Monitoring Plan.

Data are collected from the following sources:

- Sales Meeting and Product Training Sessions
- Physician Surveys

The sales training meetings were completed and a total of thirty-five (35) surveys from ten (10) countries/territories were filled out after the sales conference by members of the direct sales forces. The overall performance of the Sapphire II NC PTCA in region was rated versus their market leader(s). A combined total of 121 units of Sapphire II NC balloon catheters were evaluated by 62 physicians from May 2013 to October 2014 at 29 hospitals in Japan and across the countries of the EMEA and APAC regions, with a total of 116 evaluation forms completed and collected. Based on the feedback collected, the overall assessment for Sapphire II NC was positive and competitive against the leading product on the market, and the clinical performance of the Sapphire II NC has met the users' needs.

Sapphire NC 24 Post-production Monitoring

A combined total of sixty-two (62) units of Sapphire NC 24 catheters were evaluated by forty-three (43) physicians at twenty-eight (28) hospitals from Mar 12 to Apr 18, 2019 in Japan, with a total of fifty-seven (57) evaluation forms were received and summarized. All of the units were evaluated in Japan due to the Sapphire NC 24 was sold in Japan only then.

The survey sheets indicated that the performances of Sapphire NC 24 had gained good reputation in Japan. The Sapphire NC 24 was popularly used to treat calcified lesion and for stent post dilatation. The Sapphire NC 24 has gained good reputation of product performance, especially in crossability, high pressure and non-compliance. The overall performance of product is impressive.

Sapphire 3 Post-production Monitoring

A total of ninety-six (96) effective physician survey sheets from fifty-three (53) hospitals in Japan were received and summarized.

Ninety-six (96) survey sheets indicated that the performances of Sapphire 3 had gained good reputation in Japan. Sapphire 3 was popularly used to treat the CTO lesions, and had better crossability to crossing the occlusion lesion.

(3) Post-Market Literature Review

Literature searching identifies potential sources of clinical data for establishing clinical data relevant to the device under evaluation. The systematic literature review was planned and executed in accordance with MEDDEV 2.7/1 Rev 4 covering articles published from 1 November 2022 to 30 July 2023. The review focused on data relevant to the Sapphire PTCA Family.

Articles were included if they met the following criteria:

- Report clinical data (safety and/or performance) on the devices in scope.

A total of 6 subject device articles were identified in the search, and none of the articles met the inclusion criteria.

The use of catheters in the Sapphire PTCA Family was not identified from the results of the comprehensive literature search.

(4) Complaints and Incidents

Complaints and incidents analysis from 1 May 2022 to the end of November 2023 were reviewed for each member of Sapphire PTCA Family respectively. The low complaints rate supports the clinical safety of the Sapphire PTCA Family products.

EU Medical Device Vigilance (MDV) incident reports

Sapphire II PRO: There have been Two (2) EU Medical Device Vigilance (MDV) incident reports, one for BNHP and one for shaft damage.

Sapphire II NC: There are no Medical Device Vigilance (MDV) incident reports.

Sapphire NC 24: There are One (1) EU Medical Device Vigilance (MDV) incident reports, which is for balloon detachment.

Sapphire 3: There are One (1) EU Medical Device Vigilance (MDV) incidents reports, which is for DNC.

(5) Corrective Actions and Preventive Actions

No Corrective actions and preventive actions (CAPAs) relating to the safety and performance of the subject device were required to be conducted.

(6) Recalls And Filed Safety Corrective Actions

No recalls or filed safety and corrective actions (FSCAs) have been reported since the initial placing Sapphire products on the EU market.

(7) MAUDE Database

The MAUDE database was searched for Sapphire PTCA Family from 1 May 2022 to 30 November 2023.

Total 8 valid medical device reports (MDRs) for Sapphire II PRO were recorded, of which 7 MDRs were categorized to “injury”, 1 categorized to “malfunction”. No report of death was submitted. The most common device problem is material rupture.

One report of death for Sapphire NC 24 was submitted, which is identified as Adverse Event Without Identified Device or Use Problem. The device history record for the lot number has been reviewed. No issues or discrepancies were noted during this review that would have contributed to the reported event. No other similar complaints were received from the same lot of products up to now.

OrbusNeich medical manufacturing processes include extensive testing and inspections to ensure each product meets all material, assembly, and performance specifications prior to release.

5.4 An Overall summary of the clinical performance and safety

Clinical benefits for patients

The Sapphire family of catheters is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary artery disease evidencing coronary ischemia. The Sapphire catheters provide the clinical benefit of improving myocardial perfusion/blood flow when it is used to dilate a stenotic portion of the coronary artery thereby relieving anginal symptoms and improve exercise capacity in patients. The Sapphire family is beneficial to the acute safety and procedural success for patients undergoing PCI procedure. The Sapphire PTCA Family has a robust portfolio of clinical evidence from clinical trials, clinical data of equivalent devices, a long clinical experience as captured in prospective programs of post-market surveillance including period physician product evaluation, clinical literature search, complaints and incidents analysis, and MAUDE database. This above clinical evidence will be used to justify the safety and effectiveness of Sapphire PTCA Family and the acceptability of the benefit-risk profile of the product.

A reassessment of the clinical benefit/risk profile for Sapphire PTCA Family has concluded that the overall residual risk is acceptable and that the clinical benefits of the intended use outweigh any residual risk.

Unanticipated Side Effects or Adverse Events

There have been no unanticipated side effects or unanticipated adverse events reported in any of the identified Sapphire PTCA Family clinical investigations or in the clinical experience as captured in the Sapphire PTCA Family Post-market surveillance, complaint handling, and vigilance reporting.

5.5 Ongoing or planned post market clinical follow up

An approved PMCF plan (P190119 rev04) for Sapphire PTCA Family includes specified methods and procedures for proactively collecting and evaluating clinical data with the aim of:

- Confirming the safety and performance of the device throughout its expected lifetime,
- Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,
- Identifying and analysing emergent risks on the basis of factual evidence,
- Ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I of the MDR, and
- Identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

All PMCF collected information will be used to further evaluate the acceptability of clinical safety and effectiveness of the product family as reported annually per revision the PMCF report.

The following Table list the planned Sapphire PTCA Family PMCF activities.

Table 8, Planned Sapphire PTCA Family PMCF Activities

Activity	Description	Timeline
Physician product evaluation	Data will be collected via a Physician Evaluation Form, for the collection of physician feedback on actual clinical usage during 2 phases of the product lifecycle: a focused survey immediately after market introduction of a new product within the Sapphire PTCA Family ("New Product Evaluation" (NPE)), and continuous surveys for the collection of feedback on the entire Sapphire PTCA Family ('Product Family Evaluation" (PFE)). This survey is intended to collect at least 123 sample sizes.	Annually
Literature Review	A literature search will be conducted periodically and the methods and the outcomes will be reported in the CER.	Annually
Complaint information	Complaint information is continuously collected through the Post Market Surveilance (PMS) program	Annually

6.0 Possible diagnostic or therapeutic alternatives

Alternative therapies to Sapphire PTCA Family (coronary artery ischemia) include drug coated balloons (DCB) and devices for lesion preparation (cutting or scoring balloon angioplasty or rotational atherectomy).

The rationale for using DCB is based on the concept that with highly lipophilic drugs, even short contact times between the balloon surface and the vessel wall are sufficient for effective drug delivery. Many experimental and clinical studies have convincingly demonstrated that DCB are safe and effective. Evidence of the value of DCB in patients presenting with in-stent restenosis is overwhelming. Likewise, DCB appear

promising for selected de novo coronary lesions (including, in particular, small vessels, diffuse disease, side branches of bifurcation). Further studies are required to ascertain the relative value of DCB compared with new-generation drug-eluting stents in different clinical and anatomic scenarios.

As an important part of percutaneous coronary intervention, lesion dilatation is performed to support full stent expansion. In this scenario, cutting balloons or scoring balloons could be used for lesion preparation, and rotational atherectomy modifies undilatable calcification. Although better, and alternative technologies such as orbital atherectomy could achieve a similar function, cutting balloons, scoring balloons, or rotational atherectomy is still needed in conjunction with interventions such as DCB to achieve an optimal treatment outcome, and the continuous upgrade of the performance of the products could improve the overall outcome of the treatment.

7.0 Suggested profile and training for users

The Sapphire series should only be used by physicians trained in interventional procedures (interventional cardiologists).

8.0 Reference to any harmonized standards and CS applied

Document No.	Standard/ CS Title	Applicability
MDCG 2020-5	Clinical Evaluation – Equivalence	Used in full
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Used in full
MDCG 2019-9 Rev. 1	Summary of safety and clinical performance	Used in full
MEDDEV 2.7/1 Rev. 4	Guidelines on Medical Devices, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies, December 2016	Used in full
ISO 14155:2020	Clinical Investigation of Medical Devices in Human Subjects - Good Clinical Practice.	Used in full
ISO 14971:2019	Medical devices - Application of risk management to medical devices	Used in full
ISO 13485: 2016	Medical devices – Quality management system – Requirements for regulatory purpose	Used in full

9.0 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
01	2023/2/16	Create a new document	☒Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by NB)
02	2024/3/7	Annual update	☐Yes Validation language: ☐No