Year after year the medical environment continues to be challenging globally, and the interventional cardiology field is no exception. For example: The number of devices that can be utilized in PCI procedures in Japan is determined by the insurance reimbursement system, with the number of balloons that can be used also limited.

The Aperta NSE has an RBP of 24 atm allowing for high pressure inflation which provides for expansion at 4 atm, and through adjusting inflation pressure is a balloon that allows for expansion of a wide range of vessel sizes. Through utilizing this advantage, it is considered that Aperta can simplify the procedure while also reducing procedural costs.

We hereby report on our clinical experience in using only Aperta NSE for both pre-dilatation and post-stent dilatation.



Procedure for using Aperta NSE™ by incremental balloon inflation

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Director, Angio Center

Dr. Koichi Kishi

LACROSSE Aperta NSE™
Coronary Dilatation Catheter

ELEMENTS INTEGRATED WITH NON-COMPLIANT BALLOON

NIPRO

Case 1

70 year old male
Target lesion: Mid RCA 90%

CLINICAL HISTORY

Due to chest discomfort on effort the patient was referred to our facility.
Coronary angiogram determined occlusion at the mid-RCA (90%) and PCI was performed.

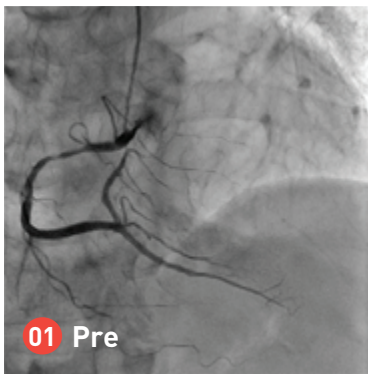
PCI

PCI was performed for a mid-RCA lesion (90%) 01. After IVUS observation 02, a 3.5x13mm Aperta NSE was selected and inflated to 8 atm from the mid to proximal RCA 03 04. Following pre-dilatation of the Aperta NSE, IVUS imaging was performed 05 and a 3.5x38mm Coroflex ISAR NEO was implanted at 10 atm 06. The same Aperta NSE was used to undertake a post-dilatation by incremental pressure from 10 to 16 atm and a dilatation of proximal RCA at 16 atm. IVUS confirmed adequate luminal gain 07, and the procedure was completed following final angiogram 08 09.

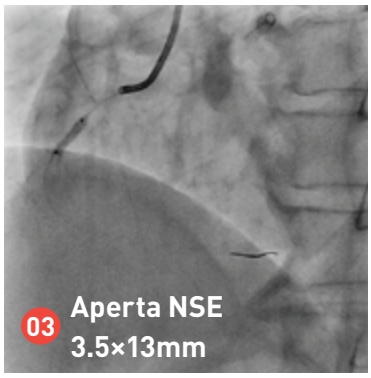
System
- Left Radial Access
- Guiding Catheter Profit BESPA 6F IL35

Target lesion
- Segment 2: 90%

Lesion characteristics
- De novo


01 Pre


02 Pre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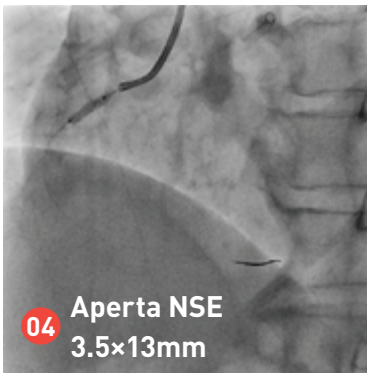
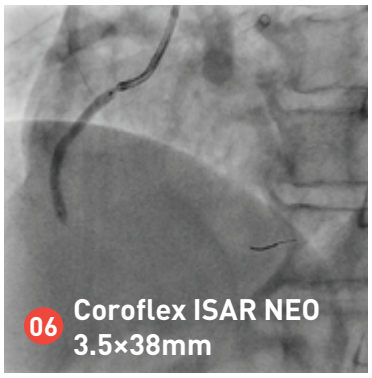
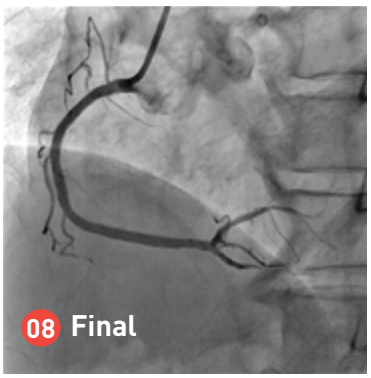
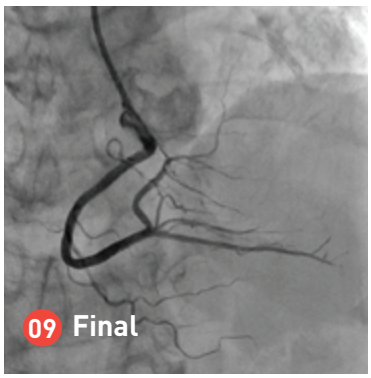

04 Aperta NSE 3.5×13mm


05 Post Aperta NSE


06 Coroflex ISAR NEO 3.5×38mm


07 Post Coroflex ISAR NEO


08 Final


09 Final

Case 2

70 year old male
Target lesion: Mid-LAD with a bifurcation

CLINICAL HISTORY

Patient was diagnosed with effort angina. Coronary angiography revealed 90% stenosis of mid-LAD bifurcation.

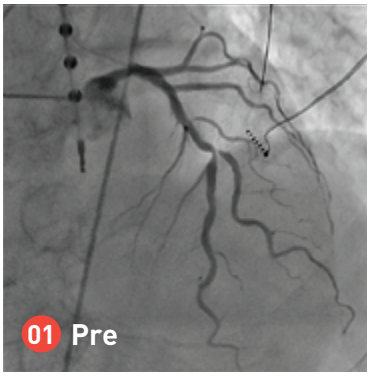
PCI

PCI was performed for a 90% mid-LAD bifurcation (1,1,1) 01. Using a 7F-SL4.0 guide catheter, an extra floppy guide wire was crossed to the main branch, and a ultra floppy wire to the diagonal. In order to avoid balloon slippage with simultaneous balloon inflation, an Aperta NSE 3.0x13mm for main vessel and an Aperta NSE 2.25x13mm for side branch were selected. IVUS confirmed slight negative remodeling at the lesion compared to proximal and distal vessel 02 03, the main vessel was inflated by incremental pressure three times from 04 to 8 atm 4. The side branch was also inflated by incremental pressure two times from 6 to 8 atm 05 and simultaneous inflation was performed using the same Aperta NSE at 6 atm 06 without incurring balloon slippage. A DES 3.0x20mm was implanted at 11 atm 07 and inflated gradually to a maximum of 14 atm. Stent malapposition was confirmed at the proximal segment, and POT (Proximal Optimization Technique) was performed with 3.5mm POBA at 12 atm 08 . Angiography showed good expansion after simultaneous inflation with Aperta 3.0mm and POBA 2.25mm (PBED - Proximal Balloon Edge Dilatation) 09 10. IVUS confirmed adequate luminal gain 11.

System
- Right Radial access
- Guiding Catheter SL 4.0 7F

Target lesion
- Segment 7: 90 % • Segment 9: 75 %

Lesion characteristics
- Bifurcation • Calcification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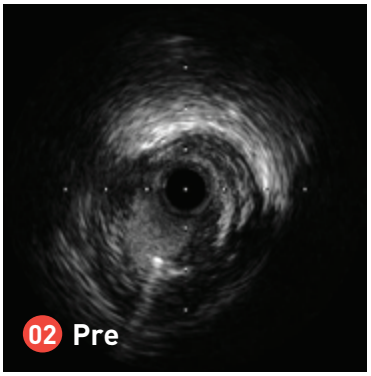
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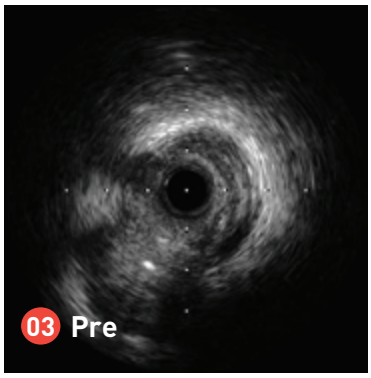
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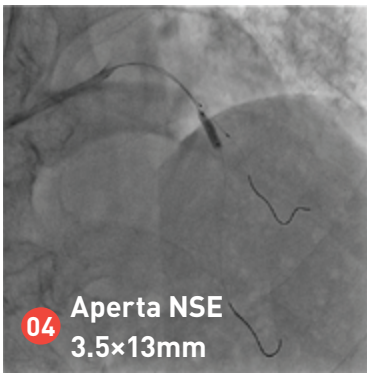
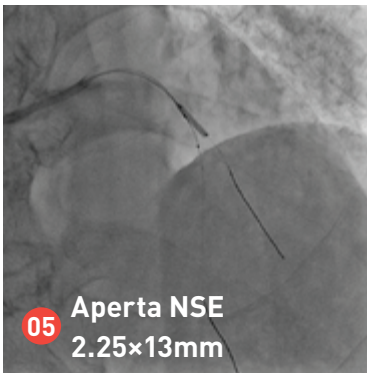

04 Aperta NSE 3.5×13mm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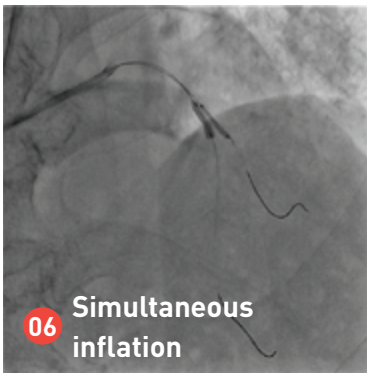
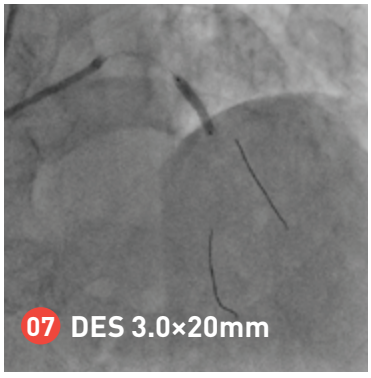
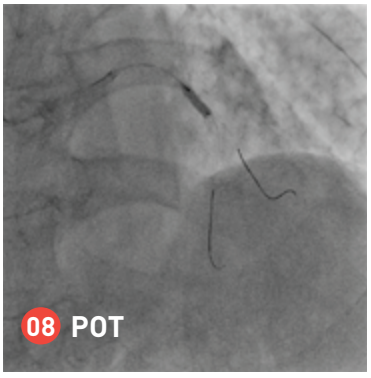
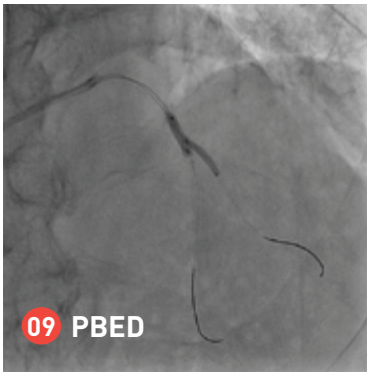

06 Simultaneous inflation


07 DES 3.0×20mm


08 POT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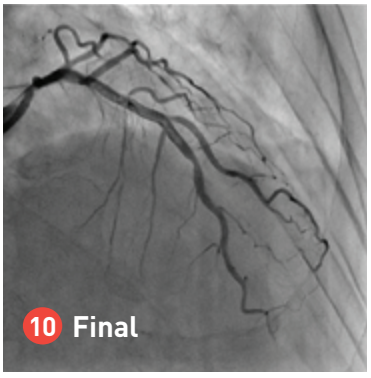
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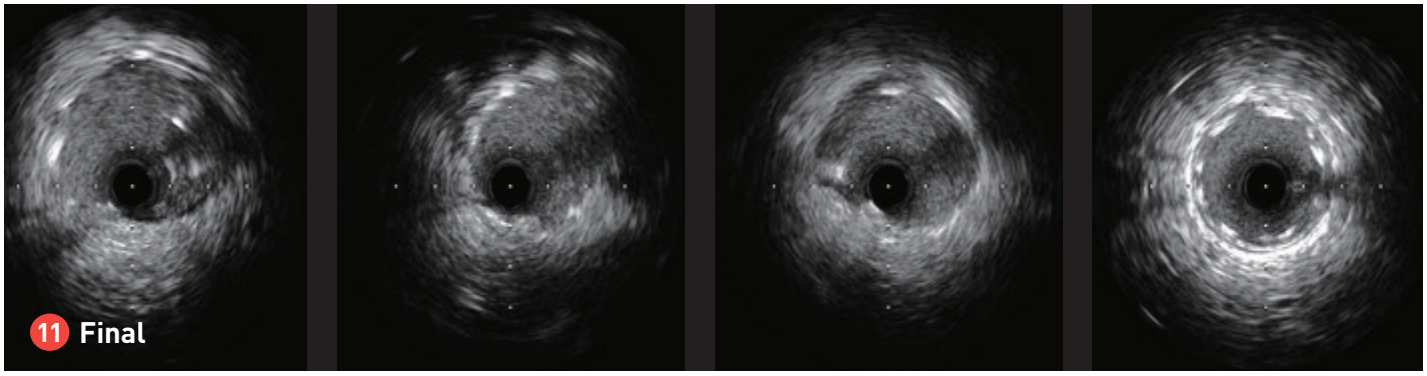

Conclusion

Due to the integration of the elements and having a non-compliant balloon platform, there may be instances whereby Aperta NSE delivery is problematic. However, due to the change in profile of the device following expansion, and through utilizing shaping of the balloon component, improvements to deliverability can be achieved. Further, dilative efficacy of the elements on a non-compliant balloon platform can be achieved for calcified lesions. Aperta NSE has a number of unique advantages over the earlier NSE version, and it is considered that through utilizing these features can provide for effective luminal gain.

COMPLIANCE CHART

Inflation Pressure		Balloon Diameter (mm)							
atm	kPa	2.00mm	2.25mm	2.50mm	2.75mm	3.00mm	3.25mm	3.50mm	4.00mm
4	4x10²	1.78	2.02	2.27	2.45	2.70	2.95	3.18	3.50
5	5x10²	1.81	2.05	2.30	2.50	2.73	2.98	3.23	3.55
6	6x10²	1.84	2.08	2.33	2.55	2.76	3.01	3.26	3.60
7	7x10²	1.86	2.11	2.36	2.59	2.79	3.04	3.29	3.65
8	8x10²	1.88	2.13	2.38	2.63	2.82	3.07	3.32	3.70
9	9x10²	1.90	2.15	2.40	2.65	2.85	3.10	3.35	3.75
10	10x10²	1.92	2.17	2.42	2.67	2.88	3.13	3.38	3.80
11	11x10²	1.94	2.19	2.44	2.69	2.91	3.16	3.41	3.85
12	12x10²	1.96	2.21	2.46	2.71	2.94	3.19	3.44	3.90
13	13x10²	1.98	2.23	2.48	2.73	2.97	3.22	3.47	3.95
14	**14x10²**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**4.00**
15	15x10²	2.02	2.27	2.52	2.77	3.02	3.27	3.52	4.02
16	16x10²	2.04	2.29	2.54	2.79	3.04	3.29	3.54	4.04
17	17x10²	2.06	2.31	2.56	2.81	3.06	3.31	3.56	4.06
18	18x10²	2.08	2.33	2.58	2.83	3.08	3.33	3.58	4.08
19	19x10²	2.09	2.35	2.60	2.85	3.10	3.35	3.60	4.10
20	20x10²	2.10	2.36	2.62	2.87	3.12	3.37	3.62	4.12
21	21x10²	2.11	2.37	2.64	2.89	3.14	3.39	3.64	4.14
22	22x10²	2.12	2.38	2.66	2.91	3.16	3.41	3.66	4.16
23	23x10²	2.13	2.39	2.68	2.93	3.18	3.43	3.68	4.18
24	**24x10²**	**2.14**	**2.40**	**2.70**	**2.95**	**3.20**	**3.45**	**3.70**	**4.20**
25	25x10²	2.15	2.41	2.72	2.97	3.22	3.47	3.72	4.22
26	26x10²	2.16	2.42	2.74	2.99	3.24	3.49	3.74	4.24
27	27x10²	2.17	2.43	2.76	3.01	3.26	3.51	3.76	4.26
								NP	RBP

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Nipro is dedicated to advancing the diagnosis and management of coronary artery disease worldwide as part of our promise to help people.

LIVE LONGER. LIVE BETTER.

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