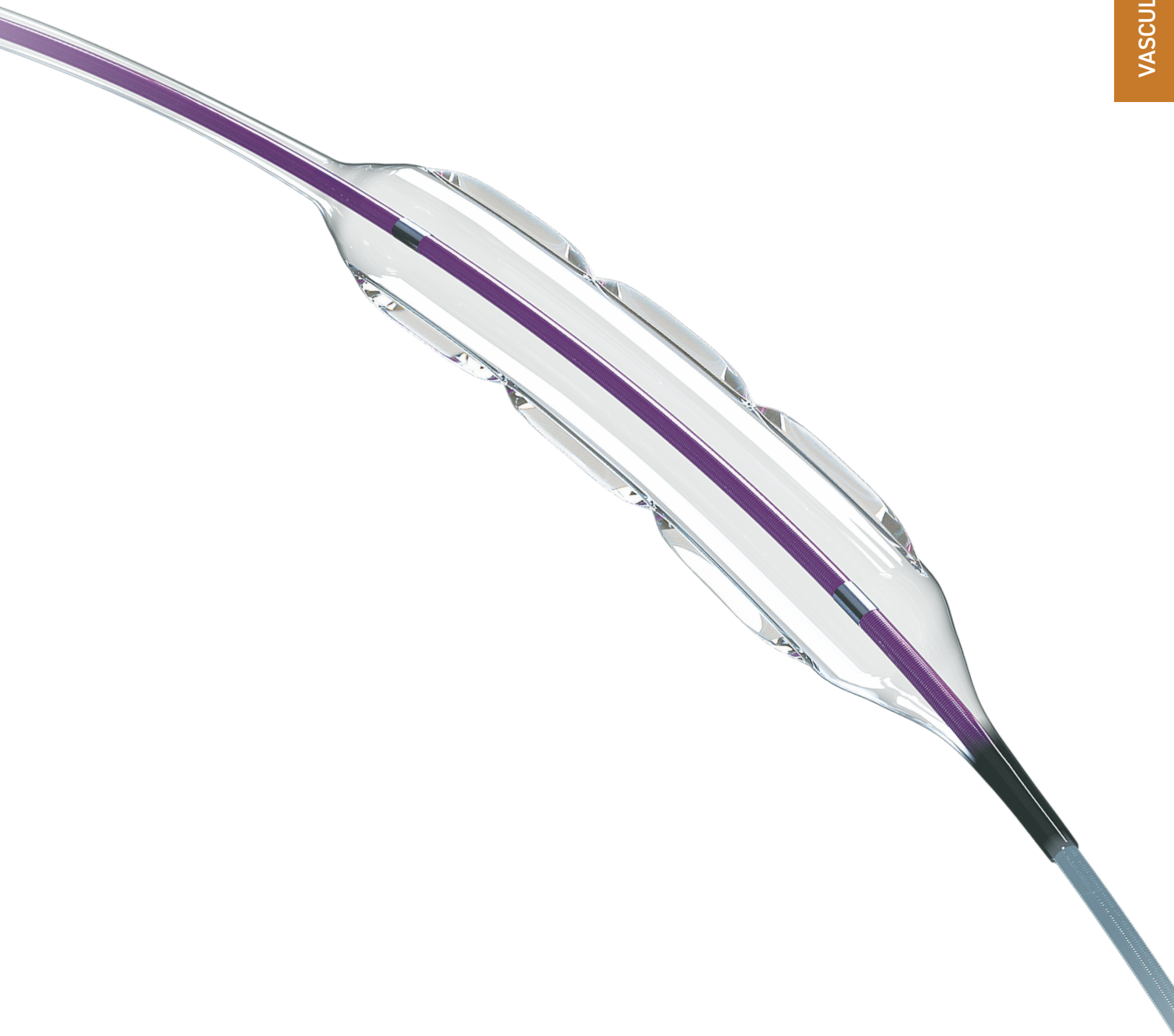


# PRODUCT DATA SHEET

VASCULAR



**Aperta NSE™**

CORONARY DILATATION CATHETER



# Aperta NSE™

A modified design to the NSE scoring balloon catheter ensures a greater scoring effect on a non-compliant platform with a lower crossing profile.

Aperta NSE™ is the next generation of NSE.

- Integrating the element with the balloon maintains the element positioning 120 degrees apart during balloon expansion.
- A non-compliant platform provides an increase in push transmission from the apex of the element.
- A reduced balloon crossing profile by eliminating the element connection.

## PRODUCT COMPLIANCE

- Complies with the following norms, directives, and regulations:

— PMDA

## MANUFACTURING DETAILS

**Legal manufacturer:** Goodman Co., Ltd. A Nipro Company

**Country of origin:** Japan

## STERILIZATION AND SHELF LIFE

### Sterilization

Ethylene Oxide



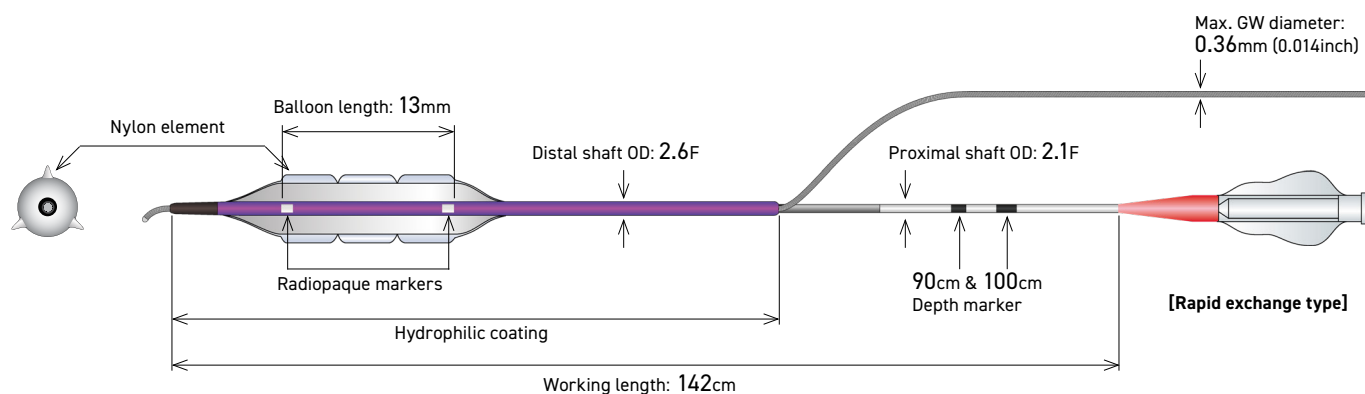
### Single-use only



### Shelf life

36 months





## PRODUCT DETAILS

### Aperta NSE™ Coronary Dilatation Catheter

#### Specifications

- 3 triangular nylon elements (0.0155" in height)
- Non-Compliant scoring balloon catheter
- NP: 14 atm and RBP: 24 atm
- 2.6 F Distal Shaft OD
- 2.1 F Proximal Shaft OD
- 1.47mm (0.058") Minimum Guiding Catheter ID

#### Lesion Indication (BISHOP)

- Bifurcation Lesion
- ISR lesion
- Small Vessel
- Hard Plaque
- Ostial Lesion
- Pre-dilatation

## ORDERING INFORMATION

| Reference code | Product name                                       |
|----------------|----------------------------------------------------|
| APN20013       | Aperta NSE™ Coronary Dilatation Catheter 2.00x13mm |
| APN22513       | Aperta NSE™ Coronary Dilatation Catheter 2.25x13mm |
| APN25013       | Aperta NSE™ Coronary Dilatation Catheter 2.50x13mm |
| APN27513       | Aperta NSE™ Coronary Dilatation Catheter 2.75x13mm |
| APN30013       | Aperta NSE™ Coronary Dilatation Catheter 3.00x13mm |
| APN32513       | Aperta NSE™ Coronary Dilatation Catheter 3.25x13mm |
| APN35013       | Aperta NSE™ Coronary Dilatation Catheter 3.50x13mm |
| APN40013       | Aperta NSE™ Coronary Dilatation Catheter 4.00x13mm |

# 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                  | 4x10 <sup>2</sup>  | 1.78                  | 2.02   | 2.27   | 2.45   | 2.70   | 2.95   | 3.18   | 3.50   |
| 5                  | 5x10 <sup>2</sup>  | 1.81                  | 2.05   | 2.30   | 2.50   | 2.73   | 2.98   | 3.23   | 3.55   |
| 6                  | 6x10 <sup>2</sup>  | 1.84                  | 2.08   | 2.33   | 2.55   | 2.76   | 3.01   | 3.26   | 3.60   |
| 7                  | 7x10 <sup>2</sup>  | 1.86                  | 2.11   | 2.36   | 2.59   | 2.79   | 3.04   | 3.29   | 3.65   |
| 8                  | 8x10 <sup>2</sup>  | 1.88                  | 2.13   | 2.38   | 2.63   | 2.82   | 3.07   | 3.32   | 3.70   |
| 9                  | 9x10 <sup>2</sup>  | 1.90                  | 2.15   | 2.40   | 2.65   | 2.85   | 3.10   | 3.35   | 3.75   |
| 10                 | 10x10 <sup>2</sup> | 1.92                  | 2.17   | 2.42   | 2.67   | 2.88   | 3.13   | 3.38   | 3.80   |
| 11                 | 11x10 <sup>2</sup> | 1.94                  | 2.19   | 2.44   | 2.69   | 2.91   | 3.16   | 3.41   | 3.85   |
| 12                 | 12x10 <sup>2</sup> | 1.96                  | 2.21   | 2.46   | 2.71   | 2.94   | 3.19   | 3.44   | 3.90   |
| 13                 | 13x10 <sup>2</sup> | 1.98                  | 2.23   | 2.48   | 2.73   | 2.97   | 3.22   | 3.47   | 3.95   |
| 14 (NP)            | 14x10 <sup>2</sup> | 2.00                  | 2.25   | 2.50   | 2.75   | 3.00   | 3.25   | 3.50   | 4.00   |
| 15                 | 15x10 <sup>2</sup> | 2.02                  | 2.27   | 2.52   | 2.77   | 3.02   | 3.27   | 3.52   | 4.02   |
| 16                 | 16x10 <sup>2</sup> | 2.04                  | 2.29   | 2.54   | 2.79   | 3.04   | 3.29   | 3.54   | 4.04   |
| 17                 | 17x10 <sup>2</sup> | 2.06                  | 2.31   | 2.56   | 2.81   | 3.06   | 3.31   | 3.56   | 4.06   |
| 18                 | 18x10 <sup>2</sup> | 2.08                  | 2.33   | 2.58   | 2.83   | 3.08   | 3.33   | 3.58   | 4.08   |
| 19                 | 19x10 <sup>2</sup> | 2.09                  | 2.35   | 2.60   | 2.85   | 3.10   | 3.35   | 3.60   | 4.10   |
| 20                 | 20x10 <sup>2</sup> | 2.10                  | 2.36   | 2.62   | 2.87   | 3.12   | 3.37   | 3.62   | 4.12   |
| 21                 | 21x10 <sup>2</sup> | 2.11                  | 2.37   | 2.64   | 2.89   | 3.14   | 3.39   | 3.64   | 4.14   |
| 22                 | 22x10 <sup>2</sup> | 2.12                  | 2.38   | 2.66   | 2.91   | 3.16   | 3.41   | 3.66   | 4.16   |
| 23                 | 23x10 <sup>2</sup> | 2.13                  | 2.39   | 2.68   | 2.93   | 3.18   | 3.43   | 3.68   | 4.18   |
| 24 (RBP)           | 24x10 <sup>2</sup> | 2.14                  | 2.40   | 2.70   | 2.95   | 3.20   | 3.45   | 3.70   | 4.20   |
| 25                 | 25x10 <sup>2</sup> | 2.15                  | 2.41   | 2.72   | 2.97   | 3.22   | 3.47   | 3.72   | 4.22   |
| 26                 | 26x10 <sup>2</sup> | 2.16                  | 2.42   | 2.74   | 2.99   | 3.24   | 3.49   | 3.74   | 4.24   |
| 27                 | 27x10 <sup>2</sup> | 2.17                  | 2.43   | 2.76   | 3.01   | 3.26   | 3.51   | 3.76   | 4.26   |

## Languages

2 languages on the IFU

English (EN), Spanish (ES)