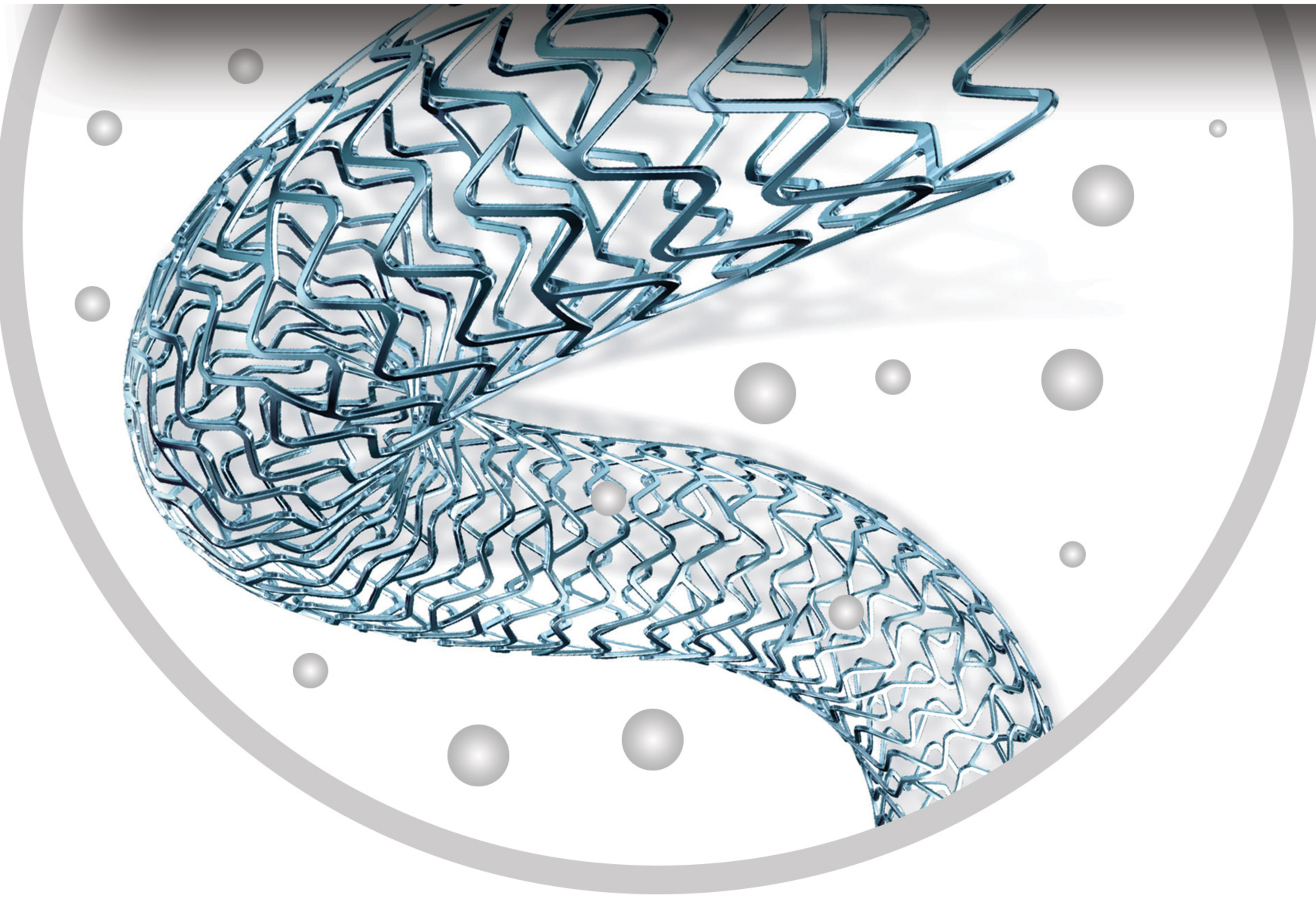
N-deavour

DRUG-ELUTING STENT



NUST
Defining futures

N-ovative
HEALTH TECHNOLOGIES
Redefining Healthcare!

Introduction

N-DEAVOUR® produced by N-ovative Health Technologies (NHT), is Pakistan's first Drug Eluting Coronary Stent System which prevents the recurrence of late stent restinosis. The drug in the mechanism is released in a controlled manner over time to not only save the coronary artery from future blockade, which is the mechanical function of a stent, but also from unhealthy cell growth as a response which has been experienced widely by patients who implant a Bare Metal Stent.

Technical Details

- **N-DEAVOUR®** is a combination product comprised of two key components: the stent (which includes a base coat of Poly Butyl Methacrylate (PBMA) and a top coat of PVDF-HFP (non-erodable polymer) and the active pharmaceutical ingredient Everolimus.

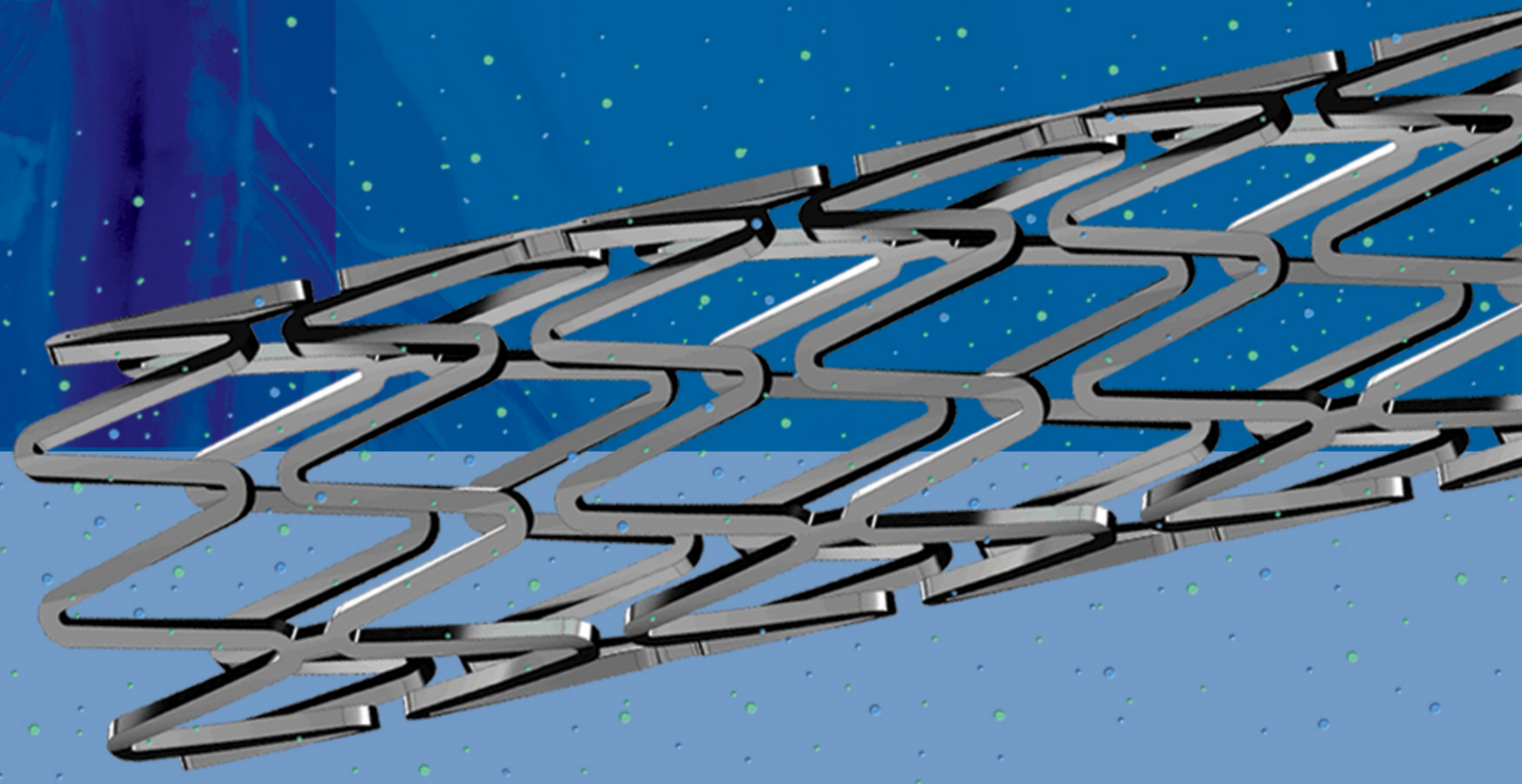
- **N-DEAVOUR®** has an MP35NLT Cobalt-Chromium (major elements include Cobalt, Nickel and Chromium) stent platform and is pre-mounted on a PTCA Balloon Dilatation Catheter.

- Everolimus is the active pharmaceutical ingredient in the **N-DEAVOUR®** stent. It is a semisynthetic macrolide immunosuppressant, synthesised by chemical modification of rapamycin (sirolimus). Drug content is 100µg/cm² Everolimus per/mm². The drug load is 100 µg/cm² for all product sizes.

- **N-DEAVOUR®** stent contains inactive ingredients including Poly N-Butyl Methacrylate (PBMA), a polymer that adheres to the stent and drug coating, and PVDF-HFP, which is comprised of vinylidene fluoride and hexafluoropropylene monomers as the drug matrix layer containing Everolimus.

- PBMA is a homopolymer with a molecular weight (Mw) of 264,000 to 376,000 dalton. PVDF-HFP is a non-erodible semi-crystalline random copolymer with a molecular weight (Mw) of 254,000 to 293,000 dalton. The drug matrix copolymer is mixed with Everolimus (83%/17% w/w polymer/Everolimus ratio) and applied to

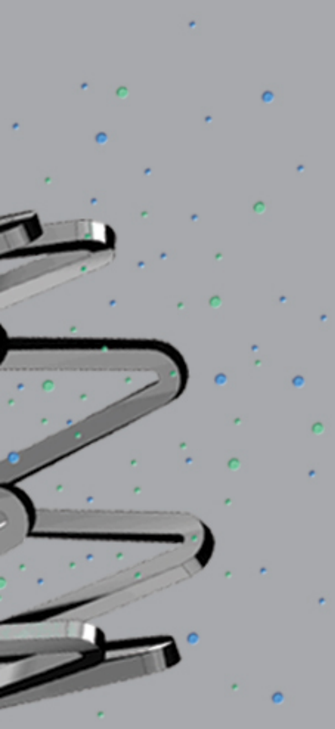
N-DEAVOUR®



Key Features

- Everolimus Eluting Stent
- Outstanding deliverability
  - Hydrophilic coated distal shaft
  - Superior trackability
  - Low lesion entry profile
- Durable polymer coating technology
- Low In-Stent Restenosis (ISR) rate
- Optimal healing
- Efficient re-endothelialisation
- Excellent biocompatibility
- Optimum durability

Item Specifications



N-Deavour® Size/ Everolimus Content	
Stent Length	**Everolimus Content**
12 mm	51.87 µg
16 mm	67.41 µg
22 mm	93.36 µg
26 mm	108.93 µg
30 mm	124.47 µg

Balloon Catheter Diameter (mm)	N-Deavour® Stent Length						
	8	12	16	18	22	26	30
2.00	A18008/ B20012	A18012/ B20016	A18016/ B20020	A18018/ B20022	A18022/ B20026	A18026/ B20030	A18030/ B20034
2.50	A18008/ B25012	A18012/ B25016	A18016/ B25020	A18018/ B25022	A18022/ B25026	A18026/ B25030	A18030/ B25034
3.00	A18008/ B30012	A18012/ B30016	A18016/ B30020	A18018/ B30022	A18022/ B30026	A18026/ B30030	A18030/ B30034
3.50	A18008/ B35012	A18012/ B35016	A18016/ B35020	A18018/ B35022	A18022/ B35026	A18026/ B35030	A18030/ B35034
4.00	A18008/ B40012	A18012/ B40016	A18016/ B40020	A18018/ B40022	A18022/ B40026	A18026/ B40030	A18030/ B40034

Product Readiness

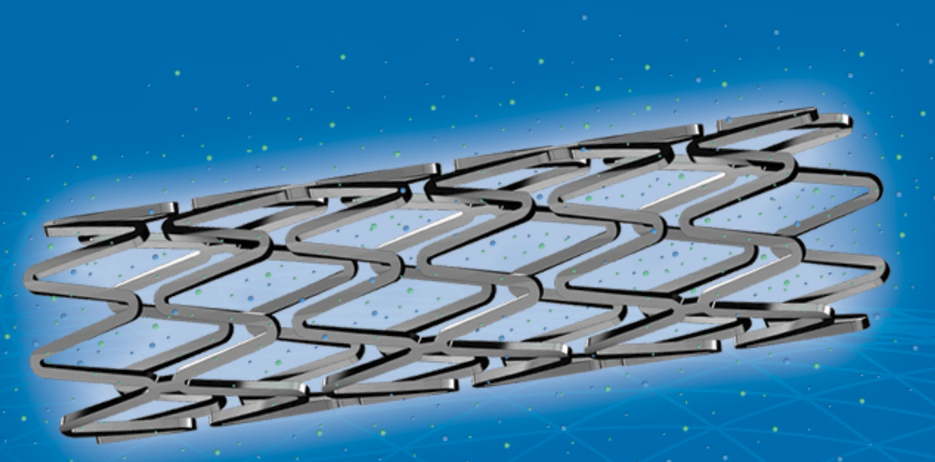
The **N-DEAVOUR®** stent system has successfully passed the following clinical evaluation stages:

1. Physico-Chemical Testing (ISO 25539) – conducted at Heinz Schade, GmbH, Germany

2. Animal trials – conducted at Centre for Cardiovascular Research and Development, American Heart of Poland

3. Human trials – in progress - in coordination with top scientists at Emory University, Atlanta, Georgia, USA

N-DEAVOUR® Everolimus Eluting Coronary Stent System comprises two components



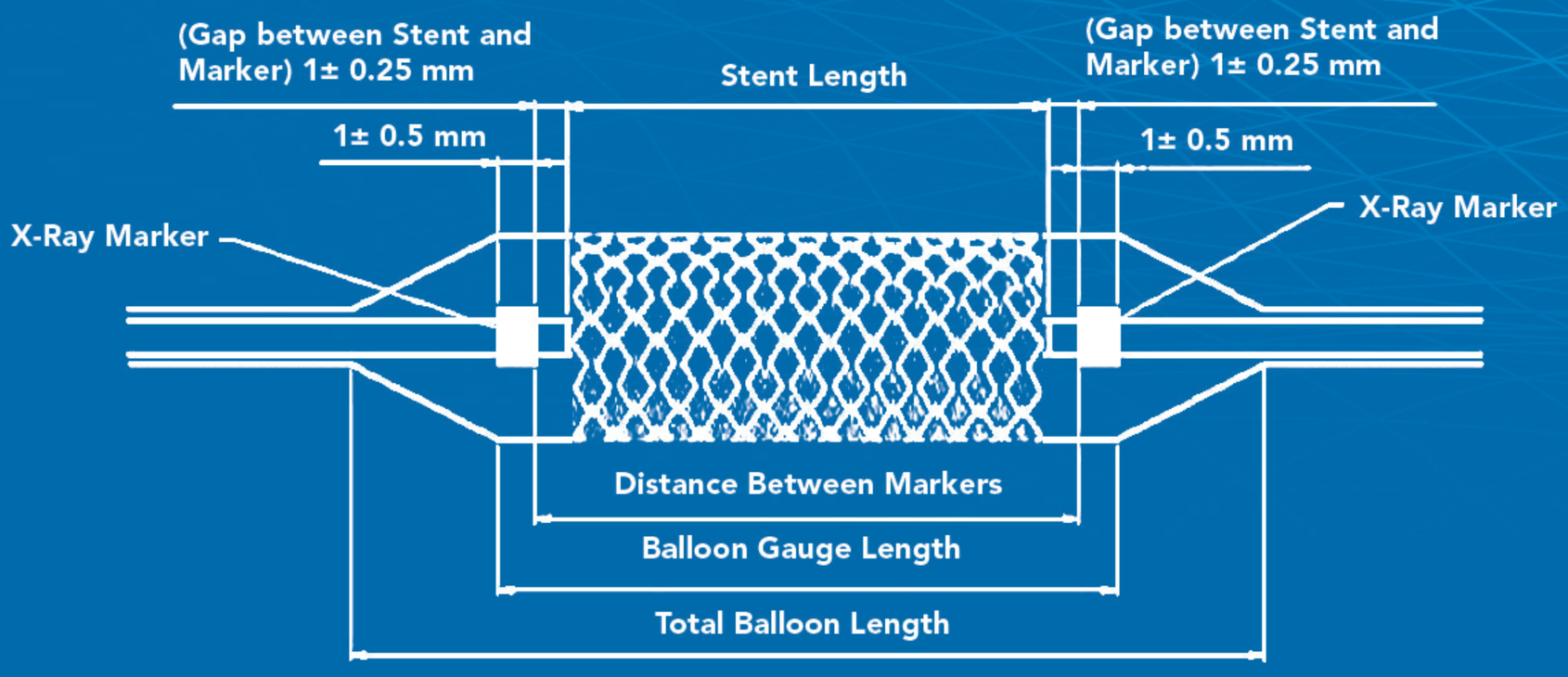
Cardiovascular Implant

Cobalt Chromium Drug Coated Stent

Delivery System

Rapid Exchange Semi Compliant Percutaneous Transluminal Angioplasty (PTCA) Balloon Catheter

- Stent is mounted (crimped) on balloon portion of catheter



- Gauge length of balloon is always kept 2±0.5 mm larger than the total length of stent.
- Length of stent has a tolerance of ±0.5mm.
- X-ray marker is placed inside the edge of gauge length of balloon, X-ray marker's width is 1±0.25 mm.
- Stent is placed in between two X-ray markers; distance from edge to edge of stent and X-ray marker is 1±0.5mm on each side.

Product Standard Compliance

N-DEAVOUR® stent is manufactured using biocompatible materials in compliance with EN ISO 10993-1 and is safe and compatible to Magnetic Resonance Imaging (MRI) environment in compliance with ASTM F2503, ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213.

N-DEAVOUR® stent has the ability to access and accurately deploy in coronary artery with fixation effectiveness keeping stent integrity with appropriate sizing to maintain luminal patency and improve luminal diameter of artery with minimum haemostasis, having ability of easy withdrawal in compliance with EN ISO 14630 and DIN EN ISO 25539-2.

N-ovative HEALTH TECHNOLOGIES

N-ovative Health Technologies (NHT) Pvt Ltd
National University of Sciences & Technology
Islamabad 44000, Pakistan
Telephone: +92-51-9085-6640, 6601
Email: cso@nhtpl.pk, info@nhtpl.pk
Website: www.nhtpl.pk

N-ovative Health Technologies Pvt Ltd

PRODUCED BY: IT NHTPL
PRINTED BY: NUST PRESS