نبض

nabd

Company Profile 2022

National Day Edition

23 September 2022

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In The Name Of Allah The Most Gracious The Most Merciful

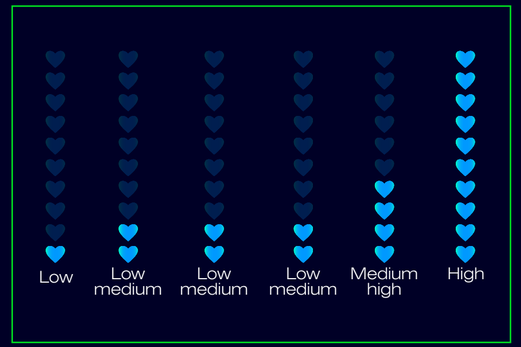
Executive Summary:

This is an introduction to NABD medical industries, which is one of the first Saudi licensed companies specialized in the production of cardiovascular medical devices used in angioplasty.

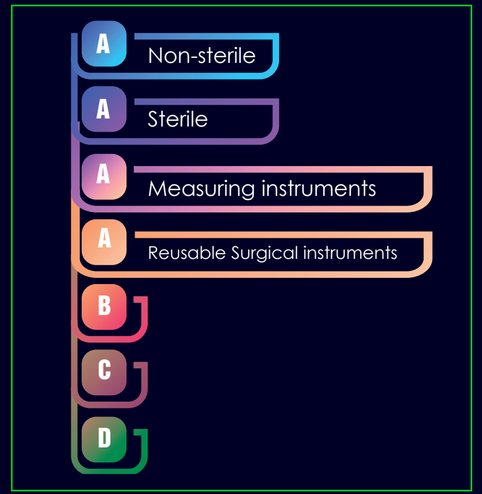
It is one of the companies that contribute to the Kingdom›s vision to improve quality of human life, this is possible through the provision of medical supplies that help in treating heart attacks and vascular occlusion cases.

Introduction

The industry of medical devices is known for its profitability in comparison to other industries. However, it is also considered one of the heavily regulated industries that requires more time to for production and approval by the different regulatory authorities both locally and internationally. The food and drug authorities usually categorize medical devices according to their level of risk on patients and the following is the standard followed by SFDA as they use the following classification that acknowledges the direct impact on the health of the individual:



Risk Class



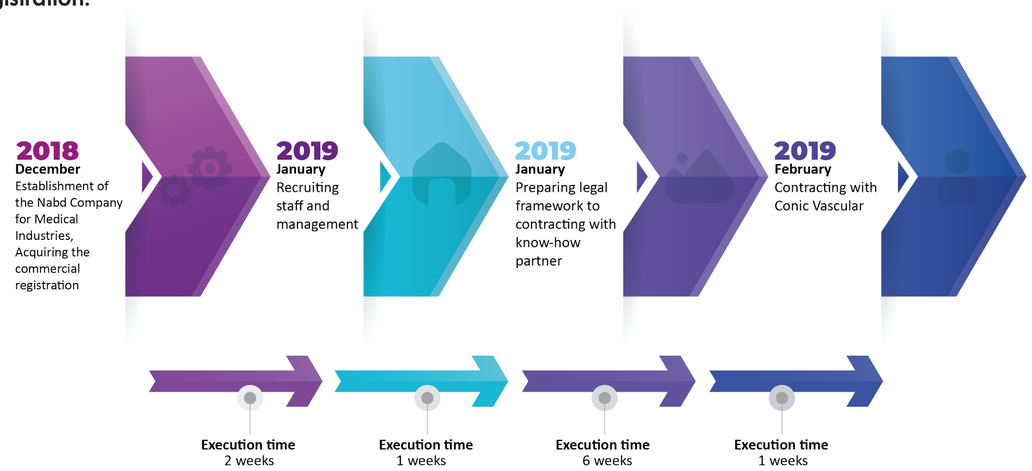
SFDA Medical Device Classification

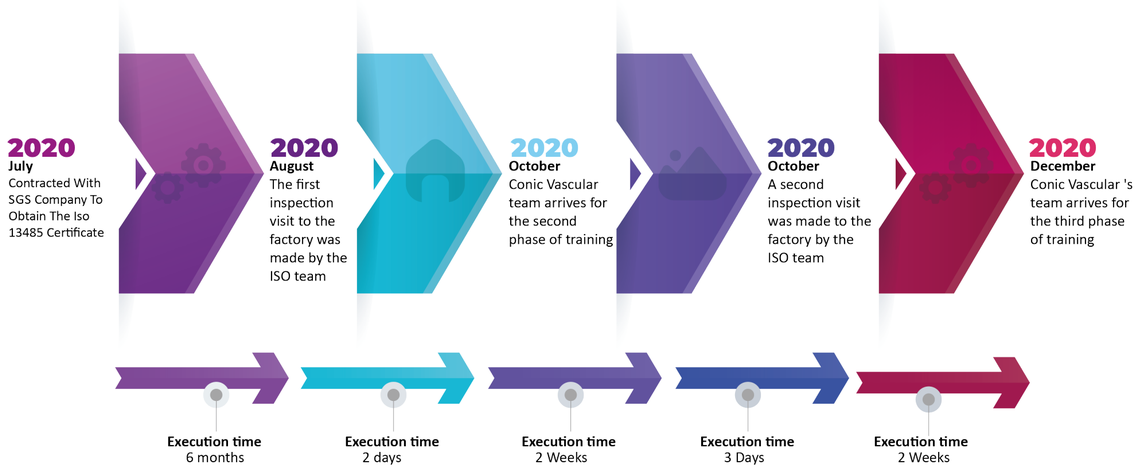
Many studies indicate that introducing a new medical device to the market takes 3 to 7 years of preparation on average. The market value of the emerging factory increases according to the number and quality of licenses obtained, as some studies indicate that the market value of the factory increases by 30 million dollars when it obtains marketing permission from the US Food and Drug Administration.
It is noticeable that the large medical companies try acquiring the emerging factories for higher prices, despite being able due to their logistical and financial ability to establish their own factories.

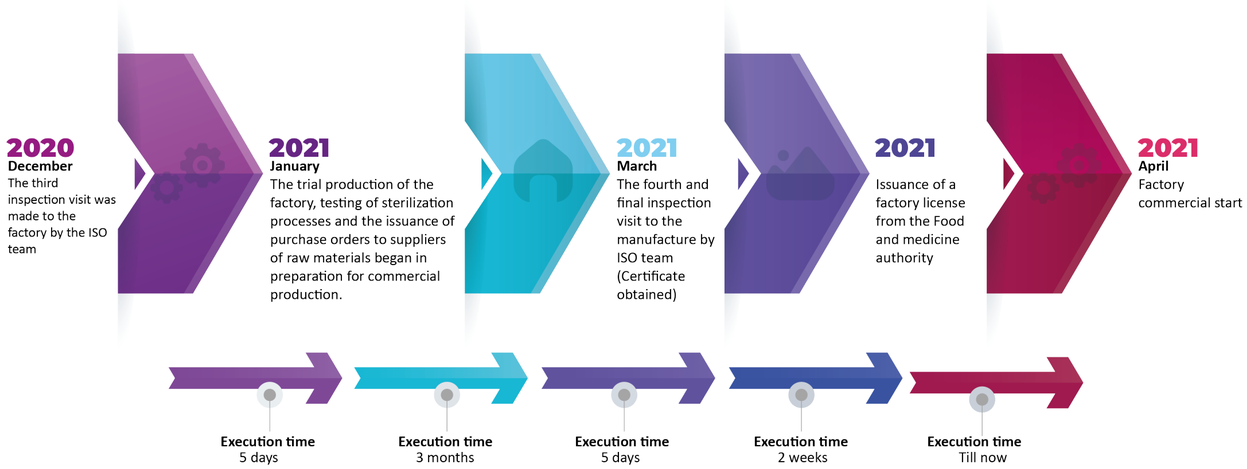
1
Project Summery

Steps of implementation

The following timeline outlines the implementation of the project since inception in 2018 till fimal products registration.




2020
July
Contracted With SGS Company To Obtain The Iso 13485 Certificate
2020
August
The first inspection visit to the factory was made by the ISO team
2020
October
Conic Vascular team arrives for the second phase of training
2020
October
A second inspection visit was made to the factory by the ISO team
2020
December
Conic Vascular 's team arrives for the third phase of training
Execution time
6 months
Execution time
2 days
Execution time
2 Weeks
Execution time
3 Days
Execution time
2 Weeks

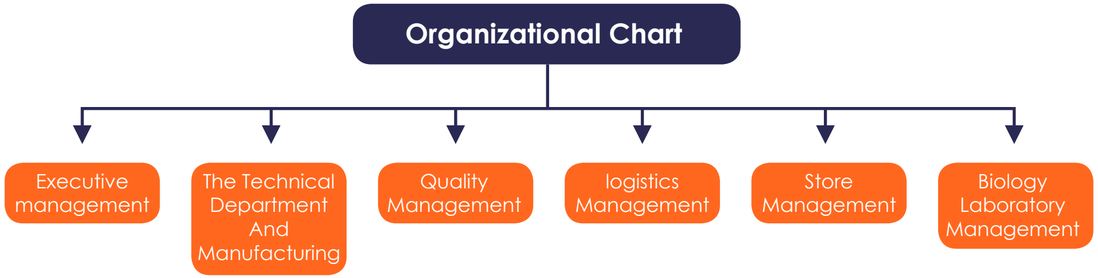

2020
December
The third inspection visit was made to the factory by the ISO team
2021
January
The trial production of the factory, testing of sterilization processes and the issuance of purchase orders to suppliers of raw materials began in preparation for commercial production.
2021
March
The fourth and final inspection visit to the manufacture by ISO team (Certificate obtained)
2021
Issuance of a factory license from the Food and medicine authority
2021
April
Factory commercial start
Execution time
5 days
Execution time
3 months
Execution time
5 days
Execution time
2 weeks
Execution time
Till now

2

Company Team

Employees:

A group of outstanding people work at the factory.
The organizational structure consists of



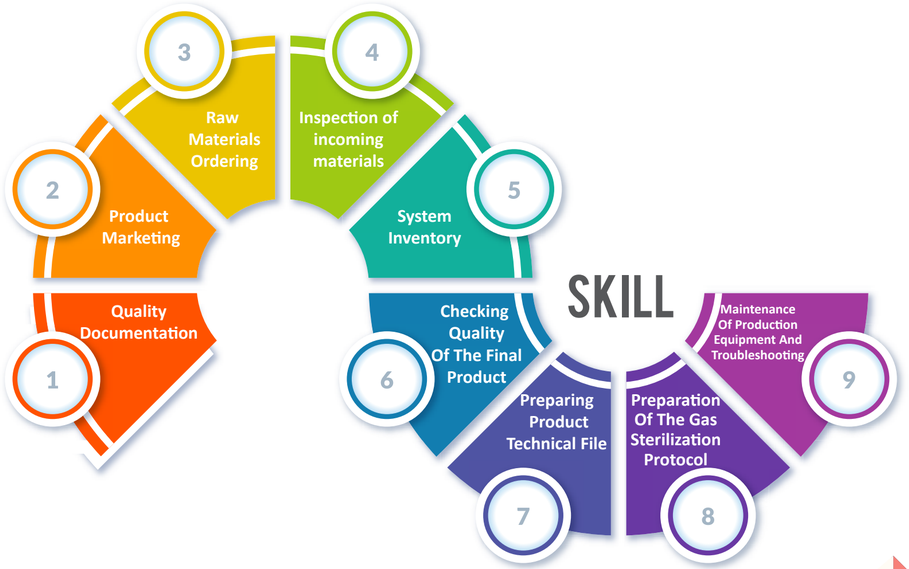
Skills Training

Operation	Certification Date
QA Documentation	20/02/2020
Material/Product Training	20/02/2020
Laser Welding	23/02/2020
Final Inspection	23/02/2020
Specification Training	24/02/2020
Cut tubing/Proximal Ball Welding	24/02/2020
Tubing Proximal/Distal Preparation	24/02/2020
Cut Wire exit	26/02/2020

Operation	Certification Date
Hot Jaw Welding	26/02/2020
Retainer preparation	26/02/2020
Balloon Folding	28/02/2020
Inner Packaging	28/02/2020
Balloon Neck Down	29/02/2020
Cut Neck to the length	29/02/2020
Balloon Control	29/02/2020
Balloon Final Inspection	29/02/2020
Assembly Marker bands	29/02/2020

Operation	Certification Date
Testing Training	12 Oct. 2020
Open/close orders	12 Oct. 2020
Prepare Balloon molds	12 Oct. 2020
Balloon Manufacturing	12 Oct. 2020
Hot Air Shrinking	12 Oct. 2020
Lure Lock Gluing	12 Oct. 2020
Label printing	12 Oct. 2020
Out package/QC Inspection/release	12 Oct. 2020

The factory management team has been trained on the following skills



3
Technical Capabilities

Medical device manufacturing facilities must meet technical requirements before the products launch to the market.
These requirements vary according to the degree of risk affiliated with the medical devic e to be manufactured. The higher the risk the higher the requirements and usually are divided to two main parts:

The first part:

It relates to preparing the medical manufacturing facility to conform with the ISO 13485 international standards for medical manufacturing.

The second part:

Verifying quality of the final product through laboratory and physical testing.
These requirements are documented in a unified technical file that includes all the requirements of good manufacturing (GMP)
NABD carried out all the works necessary to obtain certificates from the concerned authorities as follows:

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The facility licenses:

To obtain a medical facility capable of manufacturing, the following requirements must be met:

A. Class 7 sterile production room:

The production of high-risk medical supplies and devices requires the provision of a seventh-class clean room, which is characterized by its ability to filter particles with a size of 0.3 microns up to %99.9 according to ISO Standard No. -14644j.
The level of sterilization is detected and verified from an internationally accredited neutral body to assure air quality periodically.

B. Storage and support areas

The plant facilities are designed and implemented according to the requirements set forth in ISO 13485 and -14644 1 systems.
These requirements demand certain specifications in the quality of walls and floors and the way they are divided so that they are compatible with the manufacturing process.
A dedicated areas are allocated for sorting, isolating, or clearing the materials entering the factory. It also must be equipped with sensors to measure temperature and humidity and record them daily and follow a strict with pest control policy.

C. quality system:

The quality system is the measure by which the quality of the final product is verified to be free from defects and significant discrepancies through strict adherence to measurable standards to achieve homogeneity and uniformity in the product to satisfy the customers

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20

A-Industrial Establishment Licensing:

المملكة العربية السعودية
وزارة الصناعة والثروة المعدنية

VISION رؤية 2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

ترخيص منشأة صناعية

استثمار وطني

رمز المنشأة	١٠٠٠١٢٣٤	تاريخ الترخيص	١٤٤١-١٠-١٧	تاريخ القرار	١٤٤١-١٠-١٧
نوع القرار	تعديل	رقم القرار	٤١١١٠٢١٠٤٦٦٣	تاريخ الانتهاء	١٤٤٤-١٠-١٧

اسم المنشأة الصناعية	شركة نبض للصناعات الطبية	هاتف	+٩٦٦٥٥٢٢٣٣٢٢٠
السجل التجاري للمنشأة الصناعية	١٠١٠٤٧٩١٥٦	فاكس	
مالك المنشأة	شركة نبض للصناعات الطبية	موقع المنشأة الصناعية	(N24.561144518653627 ,E46.870628984113296)
رقم السجل التجاري الرئيسي	١٠١٠٤٧٩١٥٦	المنطقة	منطقة الرياض
النشاط الرئيسي	صنع المواد الصيدلانية والمنتجات الدوائية الكيميائية والنباتية / ٢١٠٠	المدينة	الرياض

عدد العمالة	٤٣	ثلاثة و أربعون فرداً
حجم الاستثمار	٢٠٥١٤٢١٣.٨٢	عشرون مليون و خمسمائة و أربعة عشر ألفا و مائتين و ثلاثة عشر ريال و إثنان و ثمانون هللة

رمز المنتج	وصف المنتج	النشاط الصناعي	الطاقة الانتاجية	الوحدة
٣٤٠٢٢٠١٠	مطهرات ومعقمات ومحاليل كيماوية مختلفة	٢٠٢٣٩٠ / أنشطة أخرى لصناعة الصابون والمطهرات ومستحضرات التنظيف والتلميع والعطورات ومستحضرات التجميل	٢٤٠٠٠٠.٠	لتر
٣٠٠٤١٠٠٠	ادوية خاصة بالجهاز الوعائي القلبي	٢١٠٠١٠ / صناعة المستحضرات الصيدلانية للاستخدام البشري	١٦٠٠٠٠.٠	وحدة

وزير الصناعة والثروة المعدنية
بندر بن إبراهيم الخريف

Ministry of Energy, Industry & Mineral Resources

Certificate
Operating license

B- Factory Operating License:

مدن MODON
الهيئة السعودية للمدن الصناعية ومناطق التقنية
Saudi Authority for Industrial Cities and Technology Zones

رخصة تشغيل

رقم الرخصة : 578144224013254
تاريخ الانتهاء : 1443/2/14

يرخص لـ :	شركة نبض للصناعات الطبية
رقم السجل التجاري :	1010479156 تاريخه : 1440/3/18 تاريخ الانتهاء : 1442/3/18
المدينة الصناعية :	الرياض الثانية
رقم العقد :	810882
موقع العقار :	0020C00:011-011

رسم توضيحي للموقع
شركة نبض للصناعات الطبية
عقد الإيجار ساري حتى : 1446/1/29 هـ

الشروط والأنظمة:

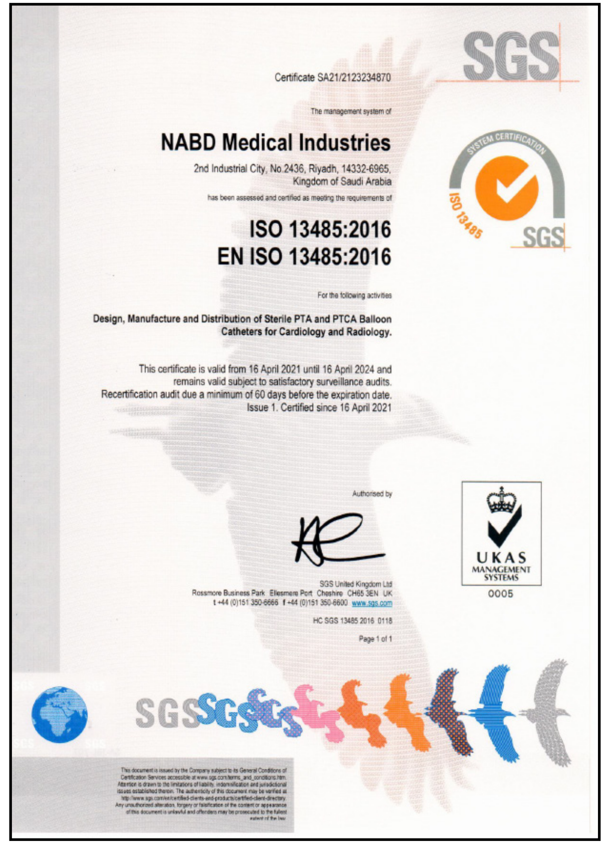
1.تعني هذه الرخصة الإذن بتشغيل المنشأة وأن المرخص له بتشغيل هذه المنشأة هو المشغل الحقيقي له وفق كيانه القانوني وتراخيصه وسجلاته ولا يحق لصاحب المنشأة التنازل عن التشغيل والرخصة أو أي جزء منها للغير..

2 .يلتزم المرخص له بالتقيد بال شروط والالتزامات المكتوبة في هذه الرخصة وبكافة الأنظمة واللوائح والشروط والتعليمات الصادرة من" مدن"، ويتم الرجوع للأنظمة واللوائح السارية المفعول المعمول بها في المملكة العربية السعودية فيما لم يرد بشأنه تنظيم لدى" مدن".

3 . .يلتزم المرخص له بتجديد هذه الرخصة خلال مدة لا تزيد عن 15 يوما بعد انتهائها.

Certificate
Facility license
industrial

c- Marketing of high-risk medical products



Certificate SA21/2123234870

The management system of

NABD Medical Industries

2nd Industrial City, No.2436, Riyadh, 14332-6965,
Kingdom of Saudi Arabia

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture and Distribution of Sterile PTA and PTCA Balloon Catheters for Cardiology and Radiology.

This certificate is valid from 16 April 2021 until 16 April 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 1. Certified since 16 April 2021

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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UKAS MANAGEMENT SYSTEMS 0005

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KINGDOM OF SAUDI ARABIA
Saudi Food & Drug Authority

VISION رؤيـة 2030

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Executive Department of Medical Devices Evaluation
Medical Devices Sector

الإدارة التنفيذية لتقييم الأجهزة الطبية
قطاع الأجهزة و المستلزمات الطبية

إذن تسويق جهاز / مستلزم طبي
Medical Device Marketing Authorization

Issuing Date: 21/3/2022	**Authorization Number:** MDMA-2-2022-0049	**رقم الإذن:**	**تاريخ الإصدار:** 18/8/1443
Expiry Date: 21/3/2023	**Version Number:** 1	**رقم الإصدار:**	**تاريخ الانتهاء:** 29/8/1444
Last Version Date: 21/3/2022			**تاريخ آخر إصدار:** 18/8/1443

The Authorization is issued in accordance with the Medical Devices Law issued by Royal Decree No. (M/54) dated 6/7/1442 HA,

أصدر هذا الإذن بموجب نظام الأجهزة والمستلزمات الطبية الصادر بالمرسوم الملكي رقم (م/54) وتاريخ 6/7/1442 هـ

This authorization allows: هذا الإذن يخول:

ML0000000420
شركة نبض للصناعات الطبية
,1,

To market the medical devices listed in the attached annex* in the Kingdom of Saudi Arabia

بتسويق الأجهزة / المستلزمات الطبية المحددة في القائمة المرفقة* في المملكة العربية السعودية

المدير التنفيذي لتقييم الأجهزة الطبية
Executive Director of Medical Devices Evaluation

د.عبد اللطيف بن سليمان الوطبان
Abdullatif S.Al Watban,Ph.D.

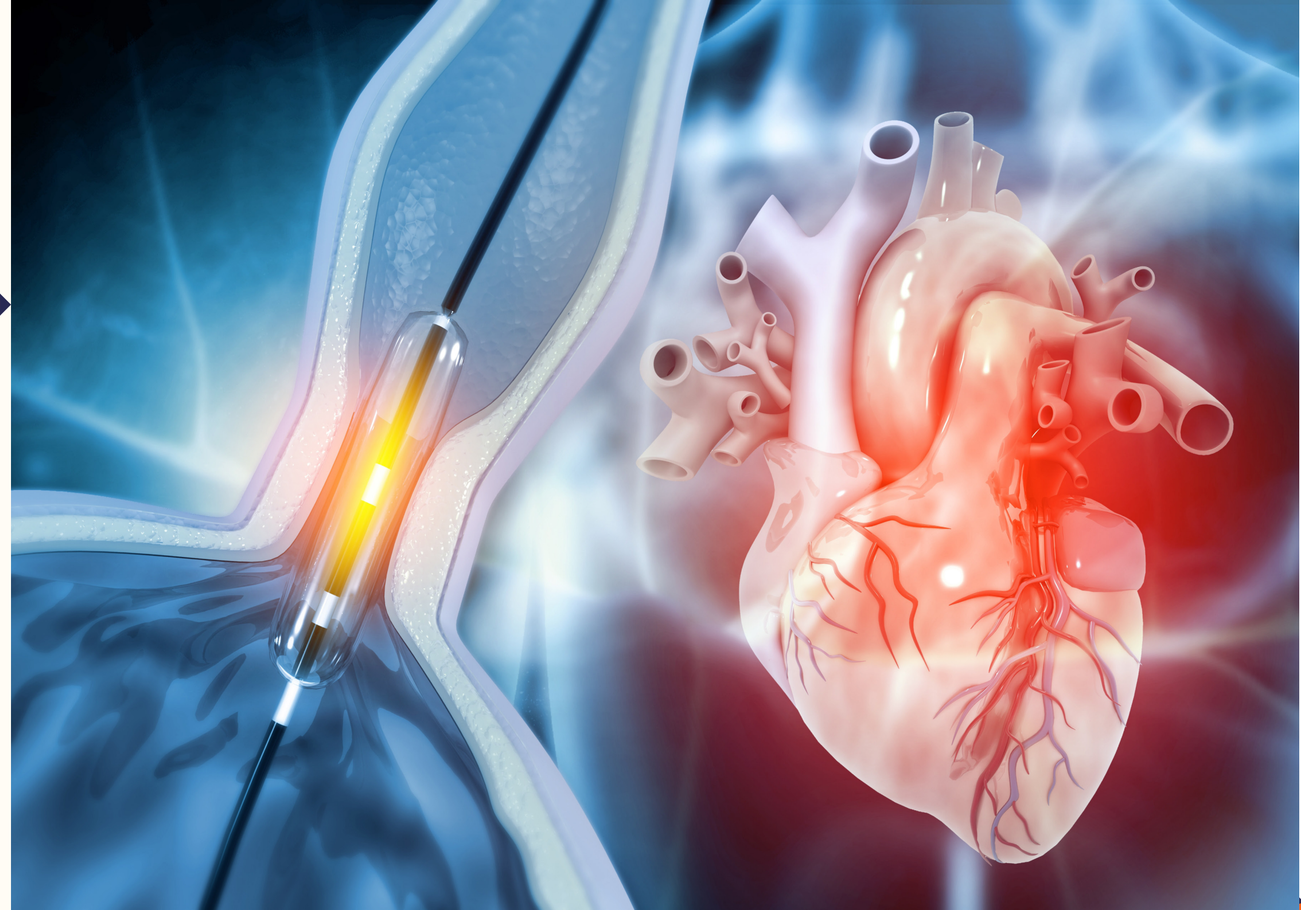
Page 1 of 2

Medical device marketing authorization March 2022

ISO 13485

4

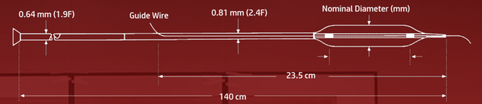
Nabd Company Products



TECHNICAL SPECIFICATIONS

- PTCA Balloon Catheter Rapid Exchange System (RX)
- Non compliant balloon dilatation catheter
- Balloon material: Polyamide
- Balloon transition angles: Tapered shoulders at 42°
- Balloon inflation pressures: Nominal 8 ATM/Bar
  Rated Burst Pressure (RBP): 20 ATM/Bar

- Catheter tip entry profile: 0.016" (0.406mm)
- Catheter length: 140 cm
- Catheter shaft diameters: 1.9 FR (proximal) and 2.4 FR (distal)
- Compatible Guidewire: 0.014" (0.357mm)
- Minimal Guiding catheter compatible: 5 FR (0.066mm)
- Kissing balloon technique: 2 balloons on 6 FR guiding catheter



ORDERING INFORMATION

BALLOON DIAMETER	BALLOON LENGTH						
	8 mm	10 mm	12 mm	15 mm	20 mm	25 mm	30 mm
1.50 mm	NC-150-8	NC-150-10	NC-150-12	NC-150-15	NC-150-20	-	-
2.00 mm	NC-200-8	NC-200-10	NC-200-12	NC-200-15	NC-200-20	NC-200-25	-
2.25 mm	NC-225-8	NC-225-10	NC-225-12	NC-225-15	NC-225-20	NC-225-25	NC-225-30
2.50 mm	NC-250-8	NC-250-10	NC-250-12	NC-250-15	NC-250-20	NC-250-25	NC-250-30
2.75 mm	NC-275-8	NC-275-10	NC-275-12	NC-275-15	NC-275-20	NC-275-25	NC-275-30
3.00 mm	NC-300-8	NC-300-10	NC-300-12	NC-300-15	NC-300-20	NC-300-25	NC-300-30
3.25 mm	NC-325-8	NC-325-10	NC-325-12	NC-325-15	NC-325-20	NC-325-25	NC-325-30
3.50 mm	NC-350-8	NC-350-10	NC-350-12	NC-350-15	NC-350-20	NC-350-25	NC-350-30
3.75 mm	NC-375-8	NC-375-10	NC-375-12	NC-375-15	NC-375-20	NC-375-25	NC-375-30
4.00 mm	NC-400-8	NC-400-10	NC-400-12	NC-400-15	NC-400-20	NC-400-25	NC-400-30
4.50 mm	NC-450-8	NC-450-10	NC-450-12	NC-450-15	NC-450-20	-	-
5.00 mm	NC-500-8	NC-500-10	NC-500-12	NC-500-15	NC-500-20	-	-

NABD MEDICAL INDUSTRIES COMPANY
2436 Second Industrial City,
Riyadh 14332-6965
Kingdom of Saudi Arabia
www.nabd.sa

SFDA MDNL No.: ML0000000123SFDAA00006

SAUDI MADE

ISO 13485 SGS

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PARENTE NC
NON COMPLIANT
PTCA Balloon Catheter

Catalogue No.: 22-0040-2 Rev. 00

PARENTE NC
NON COMPLIANT
PTCA Balloon Catheter

HIGH PRESSURE PTCA balloon catheter.
Adequate pressure resistance (Rated Burst Pressure RBP 20 ATM/Bar).

Indicated for HARD CALCIFIED lesions and POST-STENT DILATATION.
Optimum tracking & crossing: low profiles-tip entry and balloon crossing profiles (see chart).
Resistant walled balloon, flexible and optimum balloon refolding.

CONTROLLED balloon compliance to allow PRECISE diameter sizing.
Maximize wall apposition due to NC Balloon performance.

Excellent navigability properties and BALANCED pushability, trackability and crossability.
Highly efficient hydrophilic balloon and distal shaft coating with very low friction.

Inflation CENTRAL and UNIFORM dilatation with less risk to cause edge dissection.
Balloon distal transition angle design: tapered shoulders at 42°.

Freedom of motion of guide wire at high pressure balloon inflation. No risk of guide wire collapse.
Patented design of inner tube at distal catheter segment.

BALLOON COMPLIANCE CHART

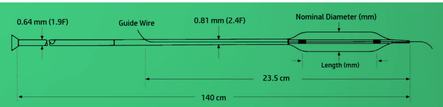
BAR / Ø	1.5 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm	4.50 mm	5.00 mm
4	1.48	1.98	2.21	2.44	2.66	2.94	3.21	3.46	3.71	3.93	4.40	4.95
6	1.49	1.99	2.23	2.47	2.72	2.98	3.23	3.49	3.74	3.98	4.48	4.98
8	1.51	2.01	2.25	2.50	2.75	3.00	3.25	3.51	3.76	4.01	4.51	5.02
10	1.52	2.02	2.27	2.52	2.77	3.02	3.28	3.53	3.78	4.05	4.55	5.05
12	1.54	2.04	2.28	2.55	2.79	3.04	3.31	3.56	3.80	4.09	4.58	5.09
14	1.55	2.05	2.30	2.57	2.81	3.07	3.35	3.58	3.81	4.11	4.61	5.13
16	1.57	2.07	2.31	2.59	2.83	3.09	3.37	3.60	3.83	4.13	4.64	5.18
18	1.59	2.09	2.33	2.61	2.85	3.11	3.40	3.63	3.85	4.15	4.66	5.22
20 RBP	1.60	2.10	2.36	2.63	2.88	3.14	3.44	3.65	3.87	4.18	4.68	5.28
22	1.62	2.12	2.39	2.65	2.91	3.16	3.46	3.67	3.89	4.20	4.71	5.31
30	30	30	30	30	30	30	30	30	28	25	25	25

PARENTE NC
PTCA NC BALLOON

TECHNICAL SPECIFICATIONS

- PTCA Balloon Catheter Rapid Exchange System (RX)
- Semi-Compliant Balloon
- Balloon material: Polyamide
- Balloon transition angles: Tapered shoulders at 42°
- Balloon inflation pressures: Nominal 6 ATM/Bar.
- Rated Burst Pressure (RBP): 18 ATM/Bar (16 ATM/Bar > 4.0 mm)

- Catheter tip entry profile 0.016" (0.406mm)
- Catheter length: 140 cm
- Catheter shaft diameters: 1.9 FR (proximal) and 2.4 FR (distal)
- Compatibility Guide wire 0.014" (0.356mm)
- Minimal Guiding catheter compatible: 5 FR (0.066") (1.65mm)
- Kissing balloon technique: 2 balloons on 6 FR guiding catheter



ORDERING INFORMATION

BALLOON DIAMETER	BALLOON LENGTH							
	10 mm	12 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm
1.00 mm	PR-100-10	PR-100-12	PR-100-15	PR-100-20	_	_	_	_
1.25 mm	PR-125-10	PR-125-12	PR-125-15	PR-125-20	_	_	_	_
1.50 mm	PR-150-10	PR-150-12	PR-150-15	PR-150-20	_	_	_	_
2.00 mm	PR-200-10	PR-200-12	PR-200-15	PR-200-20	PR-200-25	_	_	_
2.25 mm	PR-225-10	PR-225-12	PR-225-15	PR-225-20	PR-225-25	PR-225-30	PR-225-35	PR-225-40
2.50 mm	PR-250-10	PR-250-12	PR-250-15	PR-250-20	_	_	_	_
2.75 mm	PR-275-10	PR-275-12	PR-275-15	PR-275-20	PR-275-25	PR-275-30	PR-275-35	PR-275-40
3.00 mm	PR-300-10	PR-300-12	PR-300-15	PR-300-20	PR-300-25	PR-300-30	PR-300-35	PR-300-40
3.25 mm	PR-325-10	PR-325-12	PR-325-15	PR-325-20	PR-325-25	PR-325-30	PR-325-35	PR-325-40
3.50 mm	PR-350-10	PR-350-12	PR-350-15	PR-350-20	PR-350-25	PR-350-30	PR-350-35	PR-350-40
3.75 mm	PR-375-10	PR-375-12	PR-375-15	PR-375-20	PR-375-25	PR-375-30	PR-375-35	PR-375-40
4.00 mm	PR-400-10	PR-400-12	PR-400-15	PR-400-20	PR-400-25	PR-400-30	PR-400-35	PR-400-40
4.50 mm	_	PR-450-12	_	PR-450-20	PR-450-25	PR-450-30	PR-450-35	PR-450-40

NABD MEDICAL INDUSTRIES COMPANY
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Kingdom of Saudi Arabia
www.nabd.sa

SFDA MDNL No.: ML0000000123SFDAA00005

SAUDI MADE

ISO 13485 SGS

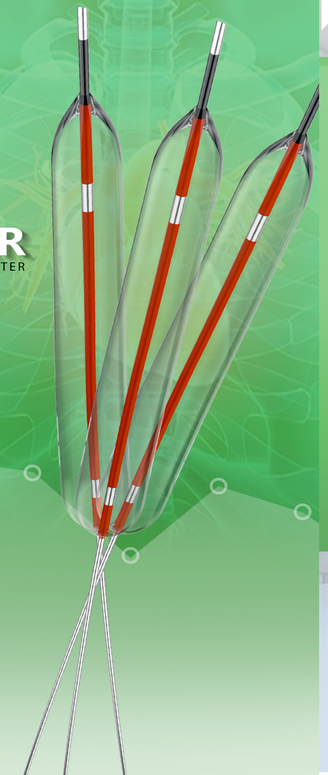
UKAS MANAGEMENT SYSTEMS 0005

nabd نبض

PARENTE REGULAR

SEMI COMPLIANT PTCA BALLOON CATHETER

Catalogue No.: 22-0040-1 Rev. 00



PARENTE REGULAR

PTCA BALLOON CATHETER

nabd نبض

Product design and patented manufacturing technology.

Excellent navigability properties and **BALANCED** pushability, trackability and crossability.

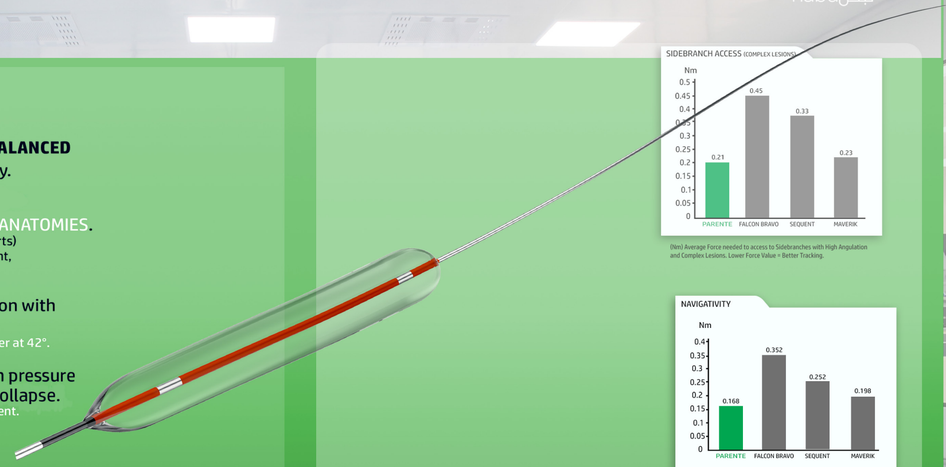
Ideal for crossing difficult and severe lesions (CTO) and TORTUOUS coronary ANATOMIES.
Low profiles - tip entry and balloon crossing. (See charts)
Very thin balloon wall (0.003 mm), very flexible, resistant, fast deflation time.

Deliver CENTRAL and UNIFORM dilatation with less risk to cause edge dissection.
Balloon distal transition angle design: tapered shoulder at 42°.

Freedom of motion of guide wire at high pressure balloon inflation. No risk pf guide wire collapse.
Patented design of inner tube at distal catheter segment.

Avoiding balloon "dog bone" effect and potential intima's injuries.
Controlled balloon growth even at high inflation pressures.

Low friction during navigation and crossability.
Highly efficient hydrophilic balloon and distal shaft coating.



(Nm) Average Force needed to access to Sidebranches with High Angulation and Complex Lesions. Lower Force Value = Better Tracking.

(Nm) Average Force needed to get the Target Lesion.
Lower Force value = Better Navigability.

BALLOON COMPLIANCE CHART

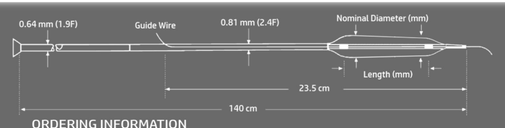
BAR	Ø 1.00 mm	1.25 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm	4.50 mm
4	0.98	1.15	1.48	1.92	2.20	2.46	2.68	2.92	3.17	3.47	3.71	3.92	4.38
6 Nom	1.00	1.24	1.52	2.05	2.28	2.54	3.76	3.04	3.27	3.54	3.74	4.04	4.50
8	1.01	1.26	1.58	2.11	2.31	2.59	2.82	3.09	3.34	3.66	3.76	4.14	4.61
10	1.02	1.27	1.64	2.14	2.37	2.66	3.88	3.15	3.40	3.71	3.78	4.22	4.69
12	1.03	1.28	1.74	2.18	2.41	2.74	3.94	3.21	3.45	3.78	3.80	4.29	4.75
14	1.05	1.30	1.78	2.22	2.45	2.82	3.99	3.25	3.49	3.88	3.81	4.36	4.80
16	1.05	1.31	1.85	2.26	2.49	2.86	3.03	3.29	3.53	3.97	3.83	4.44	4.85
18 RBP	1.06	1.33	2.00	2.30	2.53	2.90	3.07	3.34	3.57	4.04	3.85	4.54	4.93
20	1.07	1.34	2.10	2.38	2.58	2.98	3.12	3.40	3.62	4.15	3.87	_	_
22	_	_	_	_	_	_	_	_	_	_	_	_	_
23	_	_	_	_	_	_	_	_	_	>23	>23	>23	_
25	>25	>25	>25	>25	>25	>25	>25	>25	>25	_	_	_	_

PARENTE TAPERED
PTCA BALLOON CATHETER

TECHNICAL SPECIFICATIONS

- PTCA Balloon Catheter Rapid Exchange System (RX)
- Semi-Compliant Balloon
- Balloon material: Polyamide
- Parente balloon diameters: Proximal segment wider than distal segment (see PARENTE TAPERED Product references chart)
- Balloon transition angles: tapered shoulders at 42°
- Balloon inflation pressures: Nominal 8 ATM/Bar. Rated Burst Pressure (RBP): 18 ATM (16 ATM/Bar for balloons > 4.00 mm)

- Catheter tip entry profile 0.016" (0.406mm)
- Catheter length: 140 cm
- Catheter shaft diameters: 1.9 FR (proximal and 2.4 FR distal
- Compatible Guide wire 0.014" (0.356mm)
- Minimal Guiding catheter compatible: 5 FR (0.066")
- Kissing balloon technique: 2 Parente Tarered balloons on 6FR Guiding Catheter



ORDERING INFORMATION

BALLOON DIAMETER proximal / distal	BALLOON LENGTH					
	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm
1.50/1.25 mm	PT-150/125x15	PT-150/125x20				
2.00/1.50 mm			PT-200/150x25			
2.00/1.75 mm	PT-200/175x15	PT-200/175x20				
2.25/1.75 mm			PT-225/175x25	PT-225/175x30	PT-225/175x35	PT-225/175x40
2.25/2.00 mm	PT-225/200x15	PT-225/200x20				
2.50/2.00 mm			PT-250/200x25	PT-250/200x30	PT-250/200x35	PT-250/200x40
2.50/2.25 mm	PT-250/225x15	PT-250/225x20				
2.75/2.25 mm			PT-275/225x25	PT-275/225x30	PT-275/225x35	PT-275/225x40
2.75/2.50 mm	PT-275/250x15	PT-275/250x20				
3.00/2.50 mm			PT-300/250x25	PT-300/250x30	PT-300/250x35	PT-300/250x40
3.00/2.75 mm	PT-300/275x15	PT-300/275x20				
3.25/2.75 mm			PT-325/275x25	PT-325/275x30	PT-325/275x35	PT-325/275x40
3.25/3.00 mm	PT-325/300x15	PT-325/300x20				
3.50/3.00 mm			PT-350/300x25	PT-350/300x30	PT-350/300x35	PT-350/300x40
3.50/3.25 mm	PT-350/325x15	PT-350/325x20				
4.00/3.50 mm			PT-400/350x25	PT-400/350x30	PT-400/350x35	PT-400/350x40
4.00/3.75 mm	PT-400/375x15	PT-400/375x20				
4.50/4.00 mm			PT-450/400x25	PT-450/400x30	PT-450/400x35	PT-450/400x40

For selection of one PARENTE TAPERED Balloon is recommended to choose by the proximal size of balloon of each product code.

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SFDA MDNL No.: ML0000000123SFDAA00007

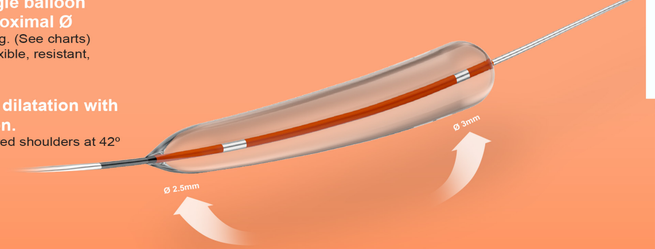
Catalogue Nr: 22-0040-3 Rev. 00

PARENTE
TAPERED
SEMI COMPLIANT PTCA BALLOON CATHETER

Excellent navigability properties and BALANCED pushability, trackability and crossability.

Ideal for CTO and TIGHT lesions.
Two small diameters in one single balloon
1.25mm distal Ø and 1.50mm proximal Ø
Low profiles - tip entry and balloon crossing. (See charts)
Very thin balloon wall (0.008 mm), very flexible, resistant, fast deflation time.

Deliver CENTRAL and UNIFORM dilatation with less risk to cause edge dissection.
Balloon distal transition angle design: tapered shoulders at 42º



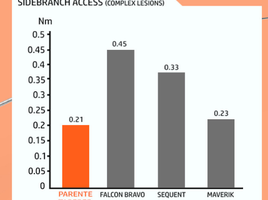
PROGRESSIVE BALLOON DIAMETER. TAPERED DESIGN MATCHING WITH CORONARY ANATOMY.

Freedom of motion of guide wire at high pressure balloon inflation. No risk of guide wire collapse.
Patented design of inner tube at distal catheter segment.

Avoiding balloon "dog bone" effect and potential intima's injuries.
Controlled balloon growth even at high inflation pressures.

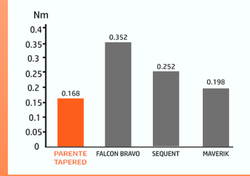
Low friction during navigation and crossability.
Highly efficient hydrophilic balloon and distal shaft coating.

SIDEBRANCH ACCESS (COMPLEX LESIONS)



(Nm) Average Force needed to access to Sidebranches with High Angulation and Complex Lesions. Lower Force Value = Better Tracking.

NAVIGATIVITY



(Nm) Average Force needed to get the Target Lesion.
Lower Force value = Better Navigability.

BALLOON COMPLIANCE CHART

Pressure (Bar)	1.25 mm	1.50 mm	1.75 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50mm	3.75 mm	4.00 mm	4.50 mm
4	1.02	1.30	1.53	1.84	1.96	2.36	2.48	2.72	2.84	3.34	3.38	3.66	4.13
6	1.23	1.45	1.61	1.92	2.16	2.51	2.68	2.99	3.15	3.49	3.59	3.93	4.36
8	1.27	1.54	1.76	2.00	2.26	2.57	2.77	3.06	3.28	3.65	3.77	4.05	4.54
10	1.32	1.58	1.83	2.04	2.34	2.62	2.83	3.13	3.35	3.72	3.96	4.13	4.57
12	1.35	1.62	1.84	2.09	2.39	2.71	2.93	3.21	3.39	3.81	4.01	4.15	4.62
14	1.39	1.67	1.87	2.18	2.42	2.75	2.99	3.26	3.57	3.94	4.11	4.20	4.68
16	1.48	1.80	1.92	2.23	2.47	2.81	3.10	3.34	3.61	4.06	4.24	4.29	4.77
18	1.61	1.88	1.94	2.28	2.52	2.85	3.25	3.37	3.70	4.13	4.40	4.38	4.82
20	1.82	2.08	1.97	2.31	2.70	2.98	3.32	3.40	3.82	4.21	4.50	4.62	>20
23										>23	>23	>23	
25	>25	>25	>25	>25	>25	>25	>25	>25	>25				
Nom	8	8	8	8	8	8	8	8	8	8	8	8	8
RBP	18	18	18	18	18	18	18	18	18	16	16	16	16

5 Company Future

NABD is currently producing cardiac and peripheral balloons, and planning to add new related products

Future Products

- Drug eluted cardiac stents
- Drug coated cardiac balloons
- Drug coated peripheral balloons
- peripheral drug eluting stents

Executive Director

Mowaffag Albayouk

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