



# The Stent with Exceptional Flexibility & Ultra-Thin Strut Thickness ( $65\mu\text{m}$ )

Trust Kamal with Your Heart.

**Stenoflex**  
Sirolimus Eluting Coronary Stent System

**Everoshine**  
Everolimus Eluting Coronary Stent System



@ [kamalmedtech.com](http://kamalmedtech.com)



CE 1434

# About The Company

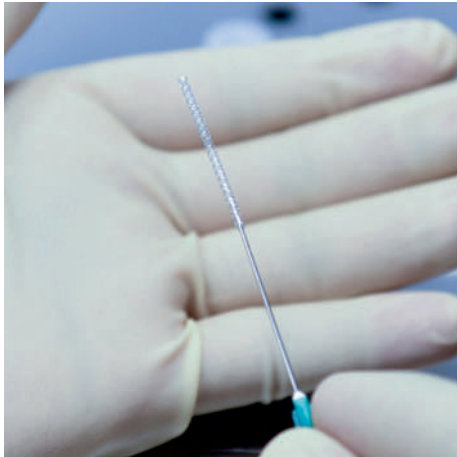


Kamal Encon Industries is engaged in diversified businesses including health care, medical devices, and also proprietary equipment for the chemical & general process industries.

Kamal's healthcare vertical was founded in 2017, in pursuit of "Better Life for All" as the next logical step to further push the agenda. What motivated Kamal to diversify into the domain of Healthcare was its commitment to providing affordable cutting-edge healthcare solutions to all. We at Kamal have been extremely passionate about living up to the highest quality standards.







# State-of-The-Art Manufacturing Facility for Cardiac Stents.

Kamal has commissioned 50,000 sq. ft. state-of-the-art manufacturing facility at Delhi-NCR. The facility has been built as per International Standard ISO 13485.

Kamal's dedicated and qualified workforce, through Amalgamation of innovation and Technology, has enabled introduction of world class quality Products and Devices which have found ready acceptance and sustained support across a broad spectrum of users worldwide. Our Healthcare vertical is committed to your success with Best in Class Medical Devices.

All Production process and Testing facilities (Microbiology, physico chemical and drug related studies) of drug eluting stent has been established at single site which resulted in superior product quality.

## R&D

Cutting Edge  
Research &  
Technology

## Quality

World-Class  
Quality Products  
& Devices

## Workforce

Kamal's  
Dedicated 400+  
Workforce

## Facility

50,000 Sq. ft  
State of the art  
manufacturing  
the facility at  
IMT Faridabad,  
Haryana





# Highly Sophisticated Production & Quality Control Equipment

## Sliding

Tornos Sliding Head Machines

## Cutting

Precise Laser System for Stent Cutting

## Cleaning

5 Stage Ultrasonic Cleaning Machine

## Coating

Customised Drug Coating Machine

## Annealing

Heating furnace with Ultrahigh Vacuum Pump

## Electropolishing

Automized EP Machine

## Crimping

Pneumatic crimped head with autosheating option

## HPLC System

For Drug Related Studies

## Stability Chamber

For Shelf Life Study



# Our Brands



## Everoshine

Everolimus Eluting Coronary Stent System

### **Everoshine Everolimus Eluting Coronary Stent System:**

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Unique stent design together with the proven efficacy of Everolimus drug & Bioresorbable polymers resulted into Everoshine with excellent safety & efficacy profile.

## ***Stenoflex***

Sirolimus Eluting Coronary Stent System

### **Stenoflex Sirolimus Eluting Coronary Stent System:**

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Innovative stent design with proven blend of anti-proliferative drug Sirolimus and Bio-degradable polymers, contributing to exceptional immediate and long term performance. Stenoflex has proven drug release kinetics.

## The Ultimate Stent With Excellent Clinical Outcomes



## Advantageous Stent Design for Complete Patient Care

Ultra-thin strut thickness of 65  $\mu\text{m}$ , for significant reduction of angiographic & clinical restenosis and reduces arterial injury <sup>1</sup>

With lower profile and smaller stent volume, Everoshine has inherent characteristics of improved flexibility and deliverability, thus navigating its path to the smaller and torturous vessels <sup>2</sup>

Thin polymer thickness of 3 $\mu$  reduces the Tissue-polymer contact and eventually reduces the polymer related disadvantages like inflammation <sup>3</sup>

The coating process allows the integrity of coated polymer after excessive stent expansion and a systemic elution of Everolimus in a well-controlled fashion after the stent implantation.

The Stent has a combination of Closed & Open cell design and features great flexibility, crossability and conformability. There are three models of stent design (as function of diameter). The design pattern is similar in each model; however, number of cells and connectors varies with the models:

**Model 1:** 2.00-2.25-2.50-2.75

**Model 2:** 3.00-3.50

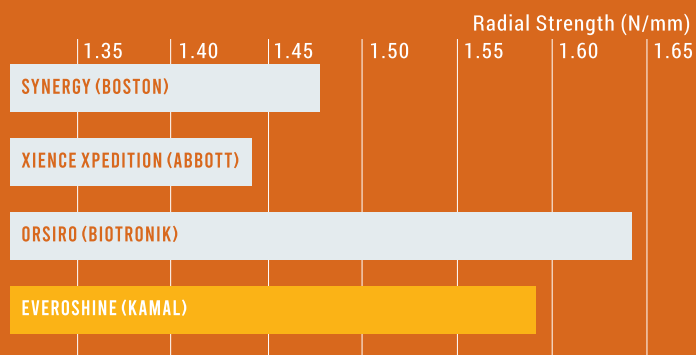
**Model 3:** 4.00-4.50



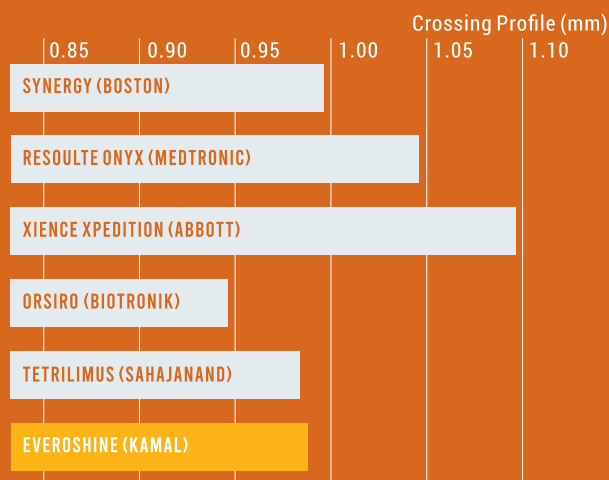
**HOMOGENOUS COATING  
RESULTS INTO OPTIMIZED  
DRUG DISTRIBUTION**

- <sup>1</sup> Intracoronary Stenting and Angiographic Results  
Strut Thickness Effect on Restenosis Outcome  
(ISAR-STERO) Trial
- <sup>2</sup> Engineering reports on file
- <sup>3</sup> Drug-eluting Stent Coatings

Higher The Radial Strength, Stronger The  
Stent And lower The Stent Recoil



Flexibility Like Never Before with Lower Stent Profile



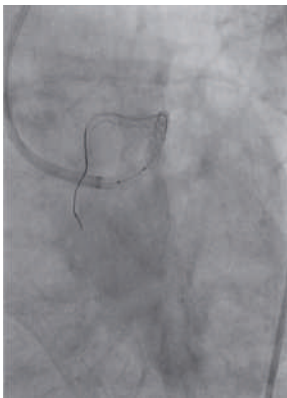


# Clinical Study Abstract

The study population included a registry of 200 patients who underwent single or multi vessel revascularization with clinical presentations such as stable angina and acute coronary syndrome in period between October 2020 and August 2021 who completes one-year follow-up period. All the patients enrolled were implanted with at least one Everoshine DES (Kamal Medtech, Faridabad, Haryana) stent and responded to follow-up. The endpoint of the study was the incidence of major adverse cardiac events (MACE) defined as cardiac death, re-infarction, repeat coronary revascularization and stent thrombosis. Clinical, telephonic follow-up was performed and MACE was analyzed at 30 days, and 12 months.



53 years old male patient with SVD-LAD-D1 bifurcation lesion with >70% stenosis in target lesion with chance of losing a significant side branch. With Everoshine stent the side branch stenting was successfully completed with resultant TIMI flow of grade 3.



71 years old female patient with diabetes and Hypertension with tight and calcified LAD lesions with 80% of stenosis. Overlapping stent implantation was successfully completed in mid-LAD with Everoshine stent without any MACE.

# Results

No. of Patients	193
No. of Lesions Treated	310
No. of Stents Used	260
Mean Age	57.8 ± 11.01 Years
Population	73.6% Males 26.4% Females
Hypertensive	47.4%
Diabetic	35.2%
Mean Lesions Length	26.77 ± 9.78 mm
Mean Stents Diameter	2.91 ± 0.39 mm
Follow Up	12 Months
End Points	
MACE	5 (2.6%) of 193
Cardiac Death	3 (1.5%)
MI	2 (0.7%)
Target Lesions Failure	2 (0.5%)
Stent Thromboses (ST)	2 (1.3%)

# Stent Specification

Design:	Combination of Closed & Open Cell Design
Material:	Cobalt Chromium (CoCr) L605
Length (mm):	8, 13, 16, 20, 24, 28, 32, 36, 40, 43 & 47
Diameter (mm):	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 & 4.50
Strut Dimensions:	Thickness: 65 µm   Strut: 70 µm   Connectors: 50 µm
Nominal Pressure (NP):	9 atm
Rated Burst Pressure (RBP):	16 atm
Foreshortening:	Nearly Zero
Recoil:	<_5%
Crossing Profile:	Nearly 1.00 mm
Min. Guidewire Diameter:	0.014"
Min. Guiding Catheter I.D.:	5 Fr Compatible
Radial Strength:	Excellent
Flexibility:	Excellent

# Stenoflex

Sirolimus Eluting Coronary Stent System

Innovative Stent for Exceptional Clinical Performance and Unmet Patient Needs



## Stenoflex The Bench Marked Stent



### Flexibility in Core Design of Stent

"FLEXIBILITY  
LIKE NEVER  
BEFORE"



The optimum and meticulously arranged cells and connectors which offers good flexibility, enabling the stent to navigate through the most tortuous coronary arteries.



### Side Branch Access

SIDE  
BRANCH  
ACCESS



The spatial arrangement of the cells, on uniform expansion contributes to ideal space for side branch access minimizing the risk of arterial injury.





## Redefining Deliverability

- Enhanced stent delivery system brings exceptional performance in complex lesion and challenging anatomy.
- A catheter shaft specifically engineered to enhance overall Pushability and Trackability.
- A catheter tubing specifically designed to improve kink resistance.

## Drug Release in Gradual Fashion Resulting in Superior Clinical Outcomes

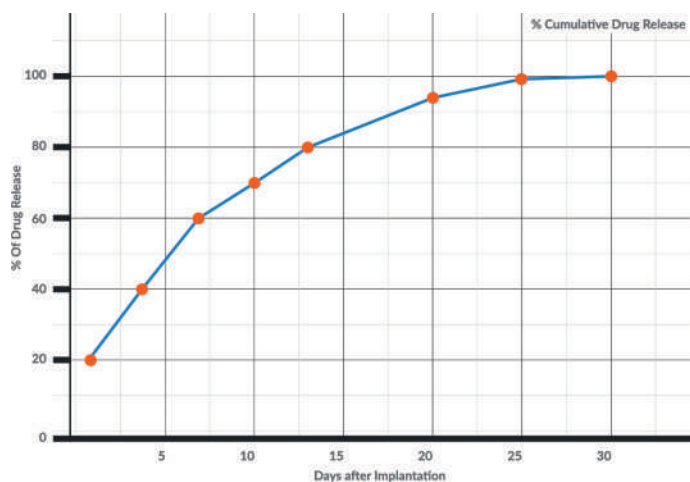
Proprietary blend of Sirolimus drug and Bioresorbable polymers provides the optimum and gradual drug release to the target site, thus providing necessary drug dose for inhibiting cell proliferation.



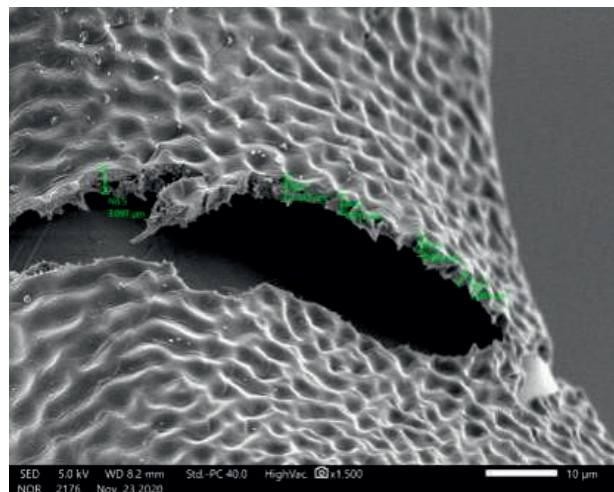
## Drug Release Kinetics:

Sirolimus has proven drug release kinetics initial burst of Sirolimus followed by sustained release up to 30 days. Bioresorbable polymers completely degrades by hydrolysis and enzymatic degradation which is excreted from the body in form of  $\text{CO}_2$  and  $\text{H}_2\text{O}$ .

## Drug Release Profile:



A very fine drug-polymer thickness of  $2\text{ }\mu\text{m}$  reduces tissue polymer contact which eventually resulted into fast remodelling of artery.



## Stent Specification

Design:	Combination of Closed & Open Cell Design
Material:	Cobalt Chromium (CoCr) L605
Length (mm):	8, 13, 16, 20, 24, 28, 32, 36, 40, 43 & 47
Diameter (mm):	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 & 4.50
Strut Dimensions:	Thickness: $65\text{ }\mu\text{m}$   Strut: $70\text{ }\mu\text{m}$   Connector Thickness: $50\text{ }\mu\text{m}$
Nominal Pressure (NP):	9 atm
Rated Burst Pressure (RBP):	16 atm
Foreshortening:	Nearly Zero
Recoil:	< 5%
Crossing Profile:	Nearly 1.00 mm
Min. Guidewire Diameter:	0.014"
Min. Guiding Catheter I.D.:	5 Fr Compatible
Radial Strength:	Excellent
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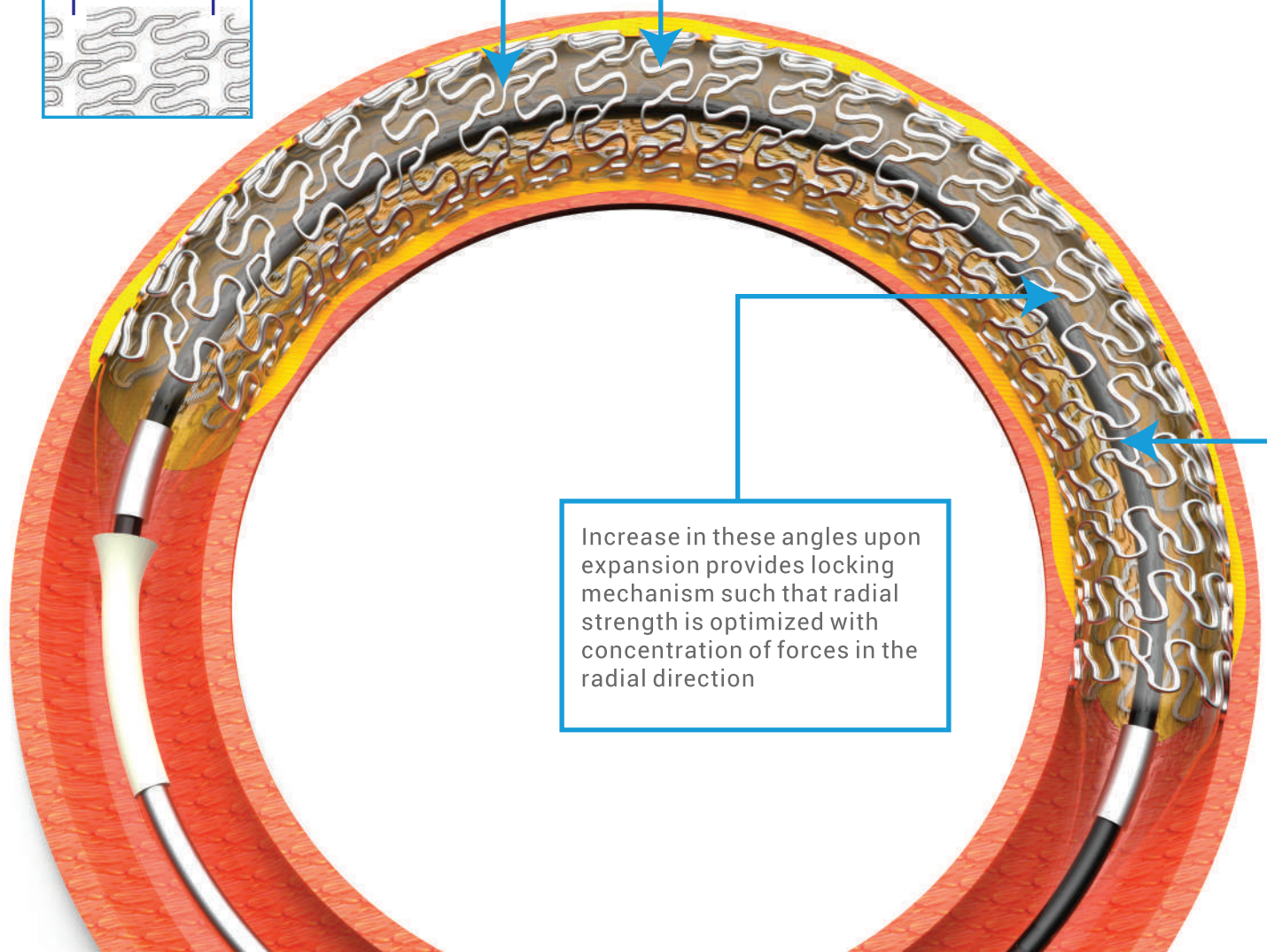
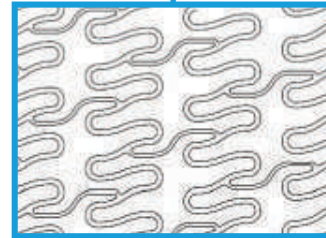
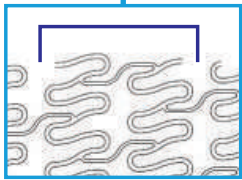
# Advantages of Our Stent Design

Optimum cell size, shape and presence of longitudinal 'S' connectors reduces the stresses during expansion and thereby prevent "Edge Flaring" & knife edge focal injury during expansion. Uniform design to allow for consistent scaffolding and support throughout the entire length of the stent without sacrificing flexibility. Further the stent & balloon match precisely to minimize Dog - Boning effect.

Ideal positioning of 'S' Connectors which originates and ends at the middle of struts, ensures zero foreshortening with relative low stress concentration in the longitudinal direction.

Mid Cells allow side branch access and homogenous stress distribution upon expansion.

Optimum cell size allows for uniform vessel wall coverage with no plaque protrusion into the stent.



Increase in these angles upon expansion provides locking mechanism such that radial strength is optimized with concentration of forces in the radial direction

# Stent Usage, Post market surveillance & Registry details

More than 1 Lac drug eluting stents have been implanted so far in real world patients since product launch in 2019. Looking at Everoshine stent clinical evaluation and the PMS registry across the country of both stents (Data collection is under progress), It is concluded that both drug eluting stents are safe & effective to use in real world patients. 15000 plus patients registry data for follow up of 2 two years ensure quality confidence and an International standard product confirmation from Leading cardiologists in India. Global Registry data being initiated & 25000 plus patients registry data will be collected in FY 2024-25.

Sr. No	Device Details	Target Patients	Registry region	Enrollment Status
1	Everoshine - Everolimus Eluting Coronary Stent System	193	Telangana	Completed
2	Trackmaster - Everolimus Eluting Coronary Stent System	1100	Madhya Pradesh	Ongoing
3	Comparative clinical evaluation of Trackmaster - Everolimus Eluting Coronary Stent System	58	New Delhi	Completed
4	Stenoflex - Sirolimus Eluting Coronay Stent System	3400	Maharashtra	Ongoing
5	Trackmaster - Everolimus Eluting Coronary Stent System	2100	Maharashtra	Ongoing
6	Trackmaster - Everolimus Eluting Coronary Stent System	500	West Bengal	Ongoing
7	Stenoplus - Sirolimus Eluting Coronary Stent System	250	West Bengal	Ongoing
8	Trackmaster - Everolimus Eluting Coronary Stent System	250	Assam	Ongoing
9	Trackflex - Sirolimus Eluting Coronary Stent System	250	West Bengal	Ongoing
10	Trackmaster - Everolimus Eluting Coronary Stent System	200	Kerala	Ongoing
11	Stenoflex - Sirolimus Eluting Coronay Stent System	2000	Gujarat	Ongoing
12	Trackflex - Sirolimus Eluting Coronay Stent System	120	Madhya Pradesh	Completed
13	Trackmaster - Everolimus Eluting Coronay Stent System	400	Gujarat	Ongoing
14	Stenoflex - Sirolimus Eluting Coronay Stent System	300	Madhya Pradesh	Ongoing
15	Everoshine - Everolimus Eluting Coronay Stent System	150	New Delhi	Ongoing
16	Stenoflex - Sirolimus Eluting Coronay Stent System	400	Rajasthan	Ongoing
17	Everoshine - Everolimus Eluting Coronay Stent System	150	Chhattisgarh	Completed



# Ordering Information



DIA (mm)	8	13	16	20	24	28	32	36	40	43	47
2.00	ER20008	ER20013	ER20016	ER20020	ER20024	ER20028	ER20032	ER20036	ER20040	ER20043	ER20047
2.25	ER22508	ER22513	ER22516	ER22520	ER22524	ER22528	ER22532	ER22536	ER22540	ER22543	ER22547
2.50	ER25008	ER25013	ER25016	ER25020	ER25024	ER25028	ER25032	ER25036	ER25040	ER25043	ER25047
2.75	ER27508	ER27513	ER27516	ER27520	ER27524	ER27528	ER27532	ER27536	ER27540	ER27543	ER27547
3.00	ER30008	ER30013	ER30016	ER30020	ER30024	ER30028	ER30032	ER30036	ER30040	ER30043	ER30047
3.50	ER35008	ER35013	ER35016	ER35020	ER35024	ER35028	ER35032	ER35036	ER35040	ER35043	ER35047
4.00	ER40008	ER40013	ER40016	ER40020	ER40024	ER40028	ER40032	ER40036	ER40040	ER40043	ER40047
4.50	ER45008	ER45013	ER45016	ER45020	ER45024	ER45028	ER45032	ER45036	ER45040	ER45043	ER45047



DIA (mm)	8	13	16	20	24	28	32	36	40	43	47
2.00	SF20008	SF20013	SF20016	SF20020	SF20024	SF20028	SF20032	SF20036	SF20040	SF20043	SF20047
2.25	SF22508	SF22513	SF22516	SF22520	SF22524	SF22528	SF22532	SF22536	SF22540	SF22543	SF22547
2.50	SF25008	SF25013	SF25016	SF25020	SF25024	SF25028	SF25032	SF25036	SF25040	SF25043	SF25047
2.75	SF27508	SF27513	SF27516	SF27520	SF27524	SF27528	SF27532	SF27536	SF27540	SF27543	SF27547
3.00	SF30008	SF30013	SF30016	SF30020	SF30024	SF30028	SF30032	SF30036	SF30040	SF30043	SF30047
3.50	SF35008	SF35013	SF35016	SF35020	SF35024	SF35028	SF35032	SF35036	SF35040	SF35043	SF35047
4.00	SF40008	SF40013	SF40016	SF40020	SF40024	SF40028	SF40032	SF40036	SF40040	SF40043	SF40047
4.50	SF45008	SF45013	SF45016	SF45020	SF45024	SF45028	SF45032	SF45036	SF45040	SF45043	SF45047

# A Better Tomorrow for All

Trust Kamal with Your Heart.



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Website



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