

Device Schedule:**Device Name:** Resolute Onyx Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The Resolute Onyx stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00000156T**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	RONYX20008X	RONYX20012X	RONYX20015X	RONYX20018X	RONYX20022X	RONYX20026X
2.25	RONYX22508X	RONYX22512X	RONYX22515X	RONYX22518X	RONYX22522X	RONYX22526X
2.50	RONYX25008X	RONYX25012X	RONYX25015X	RONYX25018X	RONYX25022X	RONYX25026X
2.75	RONYX27508X	RONYX27512X	RONYX27515X	RONYX27518X	RONYX27522X	RONYX27526X
3.00	RONYX30008X	RONYX30012X	RONYX30015X	RONYX30018X	RONYX30022X	RONYX30026X
3.50	RONYX35008X	RONYX35012X	RONYX35015X	RONYX35018X	RONYX35022X	RONYX35026X
4.00	RONYX40008X	RONYX40012X	RONYX40015X	RONYX40018X	RONYX40022X	RONYX40026X
4.50	--	RONYX45012X	RONYX45015X	RONYX45018X	RONYX45022X	RONYX45026X
5.00	--	RONYX50012X	RONYX50015X	RONYX50018X	RONYX50022X	RONYX50026X

Device Schedule (con't):**Device Name:** Resolute Onyx Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The Resolute Onyx stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B000000156T**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	RONYX20030X	--	--
2.25	RONYX22530X	RONYX22534X	RONYX22538X
2.50	RONYX25030X	RONYX25034X	RONYX25038X
2.75	RONYX27530X	RONYX27534X	RONYX27538X
3.00	RONYX30030X	RONYX30034X	RONYX30038X
3.50	RONYX35030X	RONYX35034X	RONYX35038X
4.00	RONYX40030X	RONYX40034X	RONYX40038X
4.50	RONYX45030X	--	--
5.00	RONYX50030X	--	--

Device Schedule (con't):**Device Name:** Onyx TruCor Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The Onyx TruCor stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00000156T**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.25	TRCR22508X	TRCR22512X	TRCR22515X	TRCR22518X	TRCR22522X	TRCR22526X
2.50	TRCR25008X	TRCR25012X	TRCR25015X	TRCR25018X	TRCR25022X	TRCR25026X
2.75	TRCR27508X	TRCR27512X	TRCR27515X	TRCR27518X	TRCR27522X	TRCR27526X
3.00	TRCR30008X	TRCR30012X	TRCR30015X	TRCR30018X	TRCR30022X	TRCR30026X
3.50	TRCR35008X	TRCR35012X	TRCR35015X	TRCR35018X	TRCR35022X	TRCR35026X
4.00	TRCR40008X	TRCR40012X	TRCR40015X	TRCR40018X	TRCR40022X	TRCR40026X

Device Schedule (con't):**Device Name:** Onyx TruCor Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The Onyx TruCor stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B000000156T**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.25	TRCR22530X	TRCR22534X	TRCR22538X
2.50	TRCR25030X	TRCR25034X	TRCR25038X
2.75	TRCR27530X	TRCR27534X	TRCR27538X
3.00	TRCR30030X	TRCR30034X	TRCR30038X
3.50	TRCR35030X	TRCR35034X	TRCR35038X
4.00	TRCR40030X	TRCR40034X	TRCR40038X

Device Schedule (con't):**Device Name:** Onyx Frontier Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00006588B**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	ONYXNG20008X	ONYXNG20012X	ONYXNG20015X	ONYXNG20018X	ONYXNG20022X	ONYXNG20026X
2.25	ONYXNG22508X	ONYXNG22512X	ONYXNG22515X	ONYXNG22518X	ONYXNG22522X	ONYXNG22526X
2.50	ONYXNG25008X	ONYXNG25012X	ONYXNG25015X	ONYXNG25018X	ONYXNG25022X	ONYXNG25026X
2.75	ONYXNG27508X	ONYXNG27512X	ONYXNG27515X	ONYXNG27518X	ONYXNG27522X	ONYXNG27526X
3.00	ONYXNG30008X	ONYXNG30012X	ONYXNG30015X	ONYXNG30018X	ONYXNG30022X	ONYXNG30026X
3.50	ONYXNG35008X	ONYXNG35012X	ONYXNG35015X	ONYXNG35018X	ONYXNG35022X	ONYXNG35026X
4.00	ONYXNG40008X	ONYXNG40012X	ONYXNG40015X	ONYXNG40018X	ONYXNG40022X	ONYXNG40026X
4.50	--	ONYXNG45012X	ONYXNG45015X	ONYXNG45018X	ONYXNG45022X	ONYXNG45026X
5.00	--	ONYXNG50012X	ONYXNG50015X	ONYXNG50018X	ONYXNG50022X	ONYXNG50026X

Device Schedule (con't):**Device Name:** Onyx Frontier Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00006588B**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	ONYXNG20030X	--	--
2.25	ONYXNG22530X	ONYXNG22534X	ONYXNG22538X
2.50	ONYXNG25030X	ONYXNG25034X	ONYXNG25038X
2.75	ONYXNG27530X	ONYXNG27534X	ONYXNG27538X
3.00	ONYXNG30030X	ONYXNG30034X	ONYXNG30038X
3.50	ONYXNG35030X	ONYXNG35034X	ONYXNG35038X
4.00	ONYXNG40030X	ONYXNG40034X	ONYXNG40038X
4.50	ONYXNG45030X	--	--
5.00	ONYXNG50030X	--	--

Device Schedule (con't):**Device Name:** Onyx TruStar Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00006588B**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	TSTAR20008X	TSTAR20012X	TSTAR20015X	TSTAR20018X	TSTAR20022X	TSTAR20026X
2.25	TSTAR22508X	TSTAR22512X	TSTAR22515X	TSTAR22518X	TSTAR22522X	TSTAR22526X
2.50	TSTAR25008X	TSTAR25012X	TSTAR25015X	TSTAR25018X	TSTAR25022X	TSTAR25026X
2.75	TSTAR27508X	TSTAR27512X	TSTAR27515X	TSTAR27518X	TSTAR27522X	TSTAR27526X
3.00	TSTAR30008X	TSTAR30012X	TSTAR30015X	TSTAR30018X	TSTAR30022X	TSTAR30026X
3.50	TSTAR35008X	TSTAR35012X	TSTAR35015X	TSTAR35018X	TSTAR35022X	TSTAR35026X
4.00	TSTAR40008X	TSTAR40012X	TSTAR40015X	TSTAR40018X	TSTAR40022X	TSTAR40026X
4.50	--	TSTAR45012X	TSTAR45015X	TSTAR45018X	TSTAR45022X	TSTAR45026X
5.00	--	TSTAR50012X	TSTAR50015X	TSTAR50018X	TSTAR50022X	TSTAR50026X

Device Schedule (con't):**Device Name:** Onyx TruStar Zotarolimus-Eluting Coronary Stent System**Intended Purpose as per the Instructions for Use:**

The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable**Basic UDI-DI:** 0763000B00006588B**Type:** (Code as per (EU) 2017/2185): MDN 1101**Models:**

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	TSTAR20030X	--	--
2.25	TSTAR22530X	TSTAR22534X	TSTAR22538X
2.50	TSTAR25030X	TSTAR25034X	TSTAR25038X
2.75	TSTAR27530X	TSTAR27534X	TSTAR27538X
3.00	TSTAR30030X	TSTAR30034X	TSTAR30038X
3.50	TSTAR35030X	TSTAR35034X	TSTAR35038X
4.00	TSTAR40030X	TSTAR40034X	TSTAR40038X
4.50	TSTAR45030X	--	--
5.00	TSTAR50030X	--	--