I. Intended Use / Indication

The Resistant self-expanding peripheral stent system is intended to improve luminal diameter in the treatment of symptamotic *de novo* or restenotic lesions up to 190 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.0 mm – 7.0 mm.

The Resistant self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 70 mm in length, with a reference vessel diameter of 8.0 mm – 11.0 mm.

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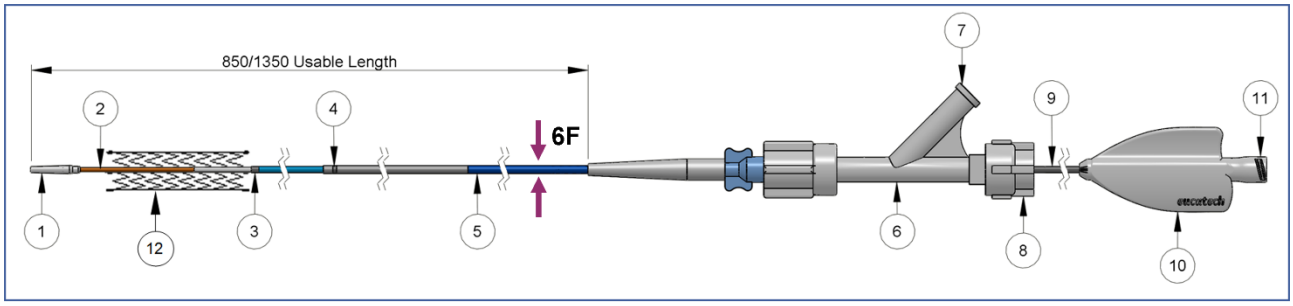
II. Device Description

The "RESISTANT" is a self-expanding peripheral Nitinol stent system for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (Nitinol) and is pre-mounted on a 6F, 0,035" over-the-wire delivery system. The delivery system is sterilized with ethylene oxide and comprises a detachable outer tube (5); an inner shaft (2); a self-expanding stent with radiopaque markers on both ends of the stent, which is constrained during application of the delivery system between the inner shaft and the outer tube; a retainer tube (3), to support the stent during deployment; a Y-connector (6) and a wing (10) for deployment of the stent, whereby via the luer-connection (7) at the Y-connector the flushing of the space in-between and via the luer-connection (11) at the wing the flushing of the guide wire lumen is done. A system lock (8) prevents the possibility of a premature deployment. At the distal end of the retainer tube and outer tube radiopaque markers (3 & 4) are located for positioning of the stent.

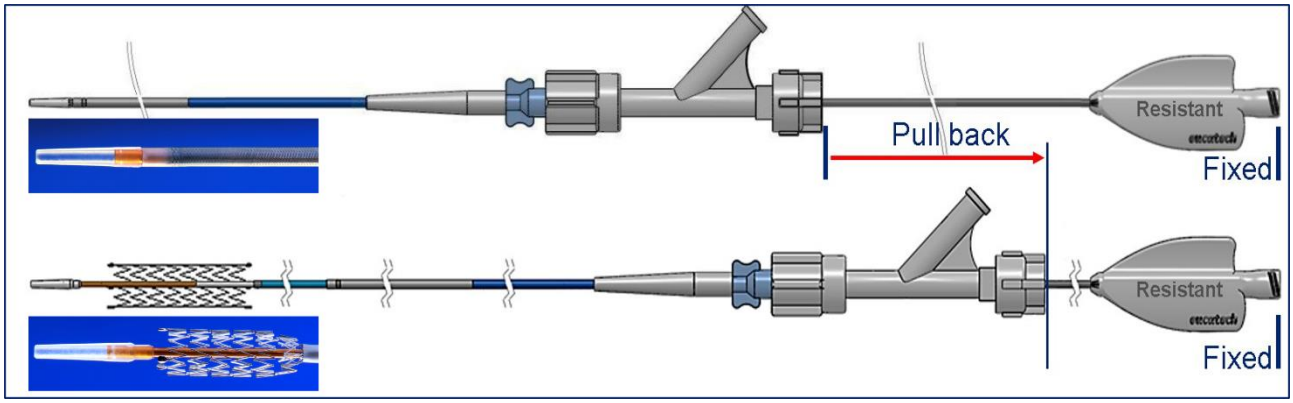


Selection of stent size is based on angiograms to determine the Reference Vessel Diameter and the Lesion Length. It is necessary to select a stent that has an unconstrained diameter at least 0.5 mm larger than the largest reference vessel diameter (RVD) to achieve secure placement according to the following stent size selection table. A higher difference between RVD and unconstrained stent diameter is leading to a higher cronical outward force towards the vessel.

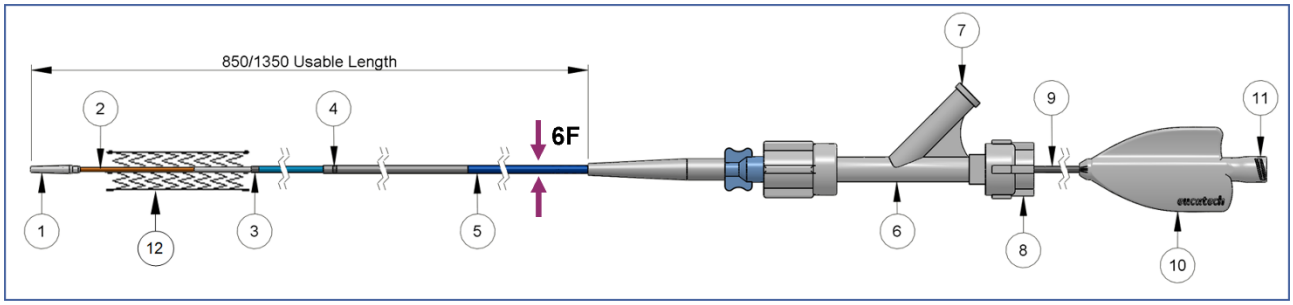
Unconstrained Stent Ø [mm]	Nominal Stent Length [mm]	Sheath Compatibility	Length Foreshortening	Reference Vessel Diameter (RVD) [mm]
5	20, 30, 40, 60, 80, 100, 120, 150, 200	6F	1.6 %	4.0 – 4.5
6	20, 30, 40, 60, 80, 100, 120, 150, 200	6F	1.8 %	5.0 – 5.5
7	20, 30, 40, 60, 80, 100, 120, 150, 200	6F	2.0 %	6.0 – 6.5
8	20, 30, 40, 60, 80, 100, 120, 150, 200	6F	2.3 %	7.0 – 7.5
9	40, 60, 80	6F	2.4 %	8.0 – 8.5
10	40, 60, 80	6F	2.6 %	9.0 – 9.5
12	40, 60, 80	6F	3.1 %	11.0 – 11.5

III. Technical Specifications

IIIa. Catheter Specifications

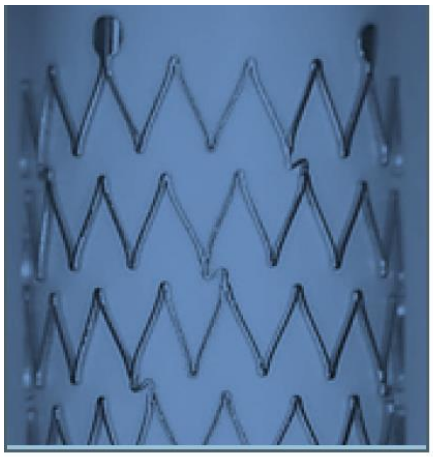
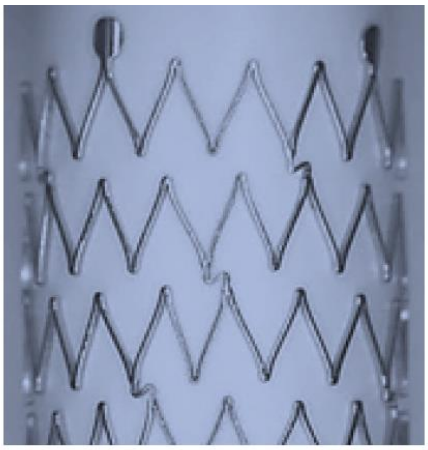
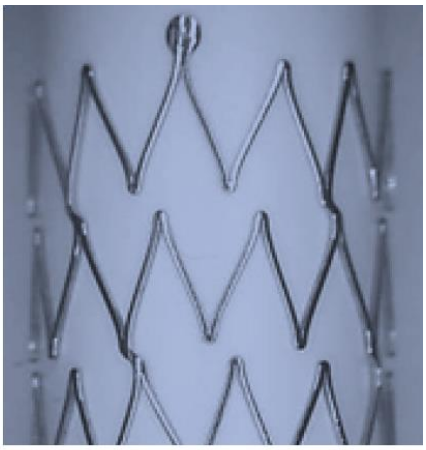


Catheter Design	**Over-The-Wire (OTW), Pull Back System**
Recommended Introducer Sheath	**6F**
Maximum Guidewire	**0.035“**
Useable Shaft Lengths	**85 cm / 135 cm (850 mm / 1350 mm)**
Tip	**Soft conical tip**
X-Ray Marker	**Distal and Proximal to Stent**
Sterilization Method	**Ethylen Oxide (ETO)**
Shelf Life	**3 years**



1 Soft Tip	7 Luer (Flushing)
2 Inner Tube	8 System Lock
3 X-Ray Marker	9 Stiffening Tube
4 X-Ray Marker	10 Hub
5 Outer Braided Tube	11 Luer (Guidewire)
6 Y-Connector	

IIIb. Stent Specifications

Ø4 – 7 mm		Ø8 mm		Ø9 – 12 mm
15 Zigzag elements 3 interlinks		16 Zigzag elements 4 interlinks		12 Zigzag elements 4 interlinks
High flexibility moderate radial strength		High flexibility moderate radial strength		High radial strenght moderate flexibility
Clinical indication				
Femoral Popliteal Tibial	Bile duct Iliac	Femoral	Bile duct Iliac	Iliac

Design	**Open Cell Design**		
Material	**Nitinol**		
Stent Diameter	**5 – 12 mm**		
Dimensions depending on diameter	**5 - 7 mm**	**8 mm**	**9 - 12 mm**
Strut Thickness	**215 µm**	**215 µm**	**215 µm**
Strut Width (Main Segment)	**113 µm**	**135 µm**	**160 µm**
Strut Width (Interlink)	**111 µm**	**113 µm**	**220 µm**
Surface finish	**Electropolishing**		
Vessel Coverage	**10 % - 22 %**		
X-Ray Marker	**3 / 4 Tantal marker distal and proximal**		

IV. Biological Characteristics

The RESISTANT stent system is compliant to EN ISO 10993-1:2010

V. Sterilization Characteristics, Shelf Life

	The device is sterilized by EO gas.
	The device has a **shelf life of 3 years**, if stored under condition specified in clause VI.
	Do not re-sterilize the device

VI. Packaging, Transportation and Storage Characteristics

Single sterile, packed in Blister sealed with Tyveck® as primary packaging. The blister is placed together with IFU in a carton box as secondary packaging. The carton box is sealed with labels.

	Do not use the device if the package is damaged
	Do not re-use the device
	Lower and upper temperature limitation
	Keep away from sunlight
	Keep dry
	Fragile, handle with care

VII. Material Specification

a) Silicone

The device does not contain any silicone.

b) Phthalates

The device does not contain any phthalates.

c) Latex

The device does not contain any latex.

d) PVC

The device does not contain any PVC.

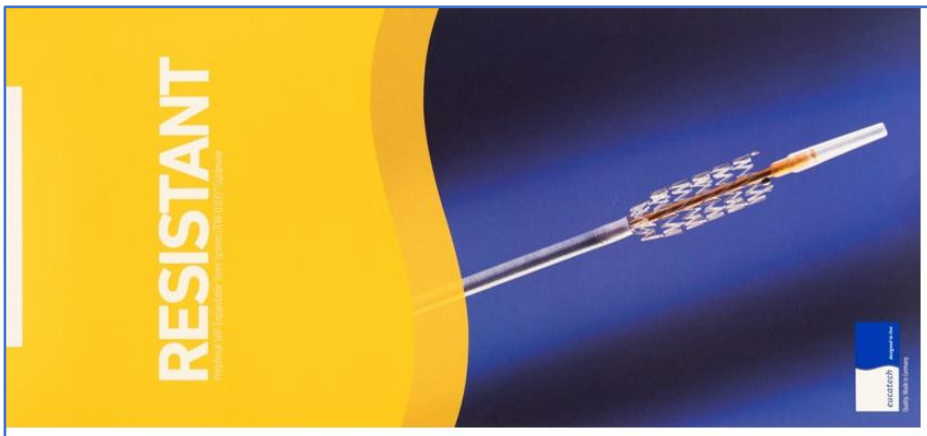
e) Animal Tissue

The device does not contain material of animal origin or derivates of animal origin.

f) Human Blood Derivates

The device does not contain any derivates based on human blood.

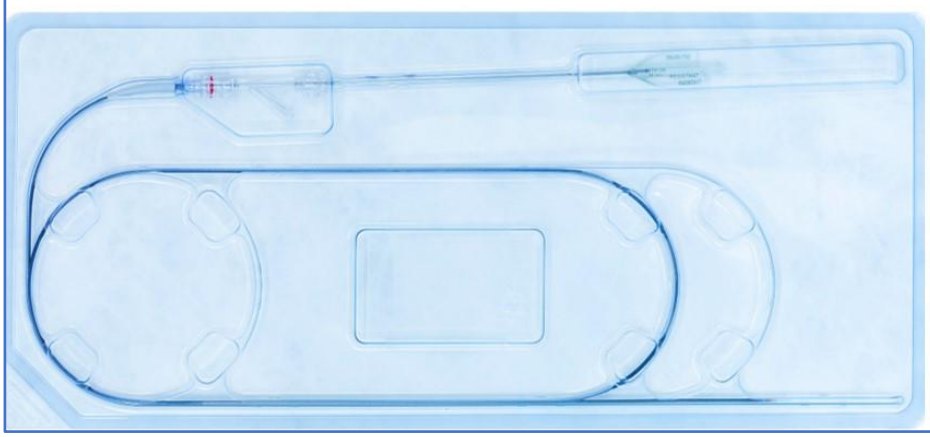
VIII. Art Work Packaging Design and Label



Front of the product packaging

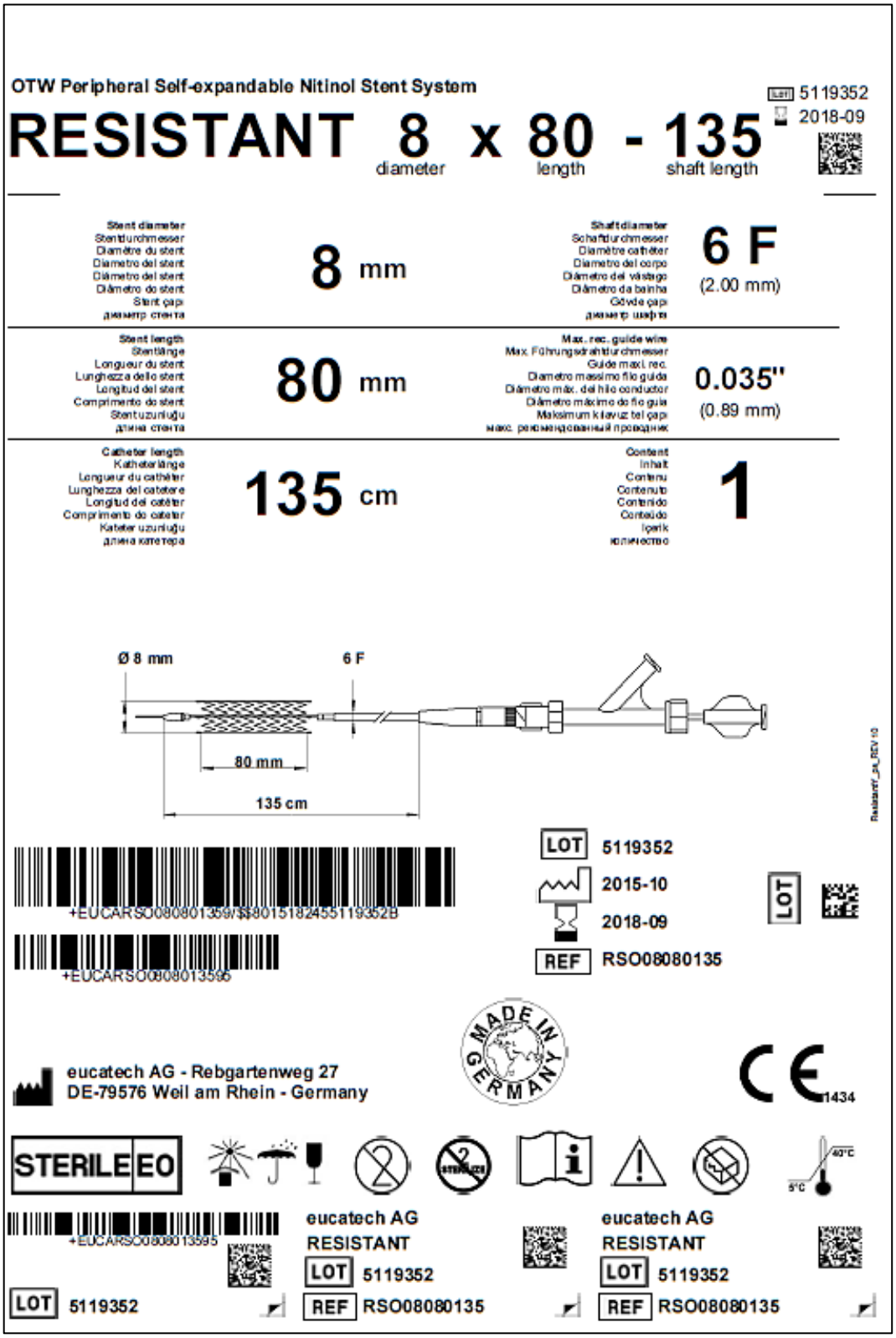
Back of the product packaging with label

Back of the blister packaging with label



Front of sterile blister packaging

IX. Label (Size 140 mm x 210 mm)



X. Size Matrix / Order Information

ORDER INFORMATION

Shaft length: 85 cm

Stent I.D.	Stent length							
	20 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm	200 mm
5 mm	RSO05020085	RSO05040085	RSO05060085	RSO05080085	RSO05100085	RSO05120085	RSO05150085	RSO05200085
6 mm	RSO06020085	RSO06040085	RSO06060085	RSO06080085	RSO06100085	RSO06120085	RSO06150085	RSO06200085
7 mm	RSO07020085	RSO07040085	RSO07060085	RSO07080085	RSO07100085	RSO07120085	RSO07150085	RSO07200085
8 mm	RSO08020085	RSO08040085	RSO08060085	RSO08080085	RSO08100085	RSO08120085	RSO08150085	RSO08200085
9 mm	–	RSO09040085	RSO09060085	RSO09080085	–	–	–	–
10 mm	–	RSO10040085	RSO10060085	RSO10080085	–	–	–	–
12 mm	–	RSO12040085	RSO12060085	RSO12080085	–	–	–	–

Shaft length: 135 cm

Stent I.D.	Stent length							
	20 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm	200 mm
5 mm	RSO05020135	RSO05040135	RSO05060135	RSO05080135	RSO05100135	RSO05120135	RSO05150135	RSO05200135
6 mm	RSO06020135	RSO06040135	RSO06060135	RSO06080135	RSO06100135	RSO06120135	RSO06150135	RSO06200135
7 mm	RSO07020135	RSO07040135	RSO07060135	RSO07080135	RSO07100135	RSO07120135	RSO07150135	RSO07200135
8 mm	RSO08020135	RSO08040135	RSO08060135	RSO08080135	RSO08100135	RSO08120135	RSO08150135	RSO08200135

XI. CE-Certification

CE Marking according	Medical Device Directive 93/42 / EEC, Annex II
Classification of Device	Class IIb
Notified Body	Polish Center for Testing and Certification (PCBC)
CE Number	CE1434
Certificate Number	1434-MDD-301/2020 1434-MDD-301/2020 ANNEX 1
CE-Certificate valid until	2024-05-27

Digitally signed by Chirtoacă Iurie
Date: 2022.10.07 17:45:00 EEST
Reason: MoldSign Signature
Location: Moldova