



# Minimizing Burden, the effect of **thin strut** and **low Chronic Outward Force SE** stents

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# Disclosure



Speaker name:

**Prof. Yong LIU**

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

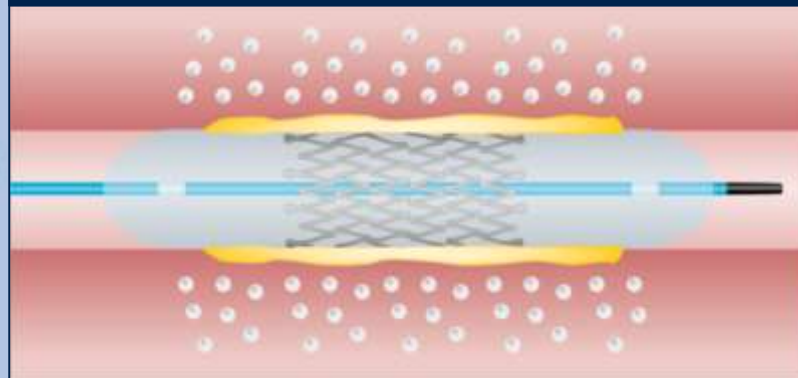
# BARE-METAL STENTS play a role as definitive or adjunctive treatment options



## SFA stents are proven as a standalone therapy

STUDY	DEVICE	Av. Lesion Length.	PP	FTLR
4EVER <sup>1</sup>	Pulsar-18	10.8 cm	73.4%	85.2%
PEACE <sup>2</sup>	Pulsar-18	11.2 cm	79.5%	81.0%
RESILIENT <sup>3</sup>	Lifestent	6.2 cm	81.3%	87.3%
DURABILITY II <sup>4</sup>	EverFlex	8.9 cm	77.2%	N/A
SUPERB <sup>5</sup>	Supera	9.0 cm	84.7%	N/A
DURABILITY <sup>6</sup>	EverFlex	9.6 cm	72.2%	79.1%

## Stents may complement DCB and are an alternative to DES



### DCB +/- Stent vs. DES

- Ability to spot stent rather than full metal burden associated with DES
- Provisional stent choice based on lesion type
  - Crush resistance in Ca<sup>+++</sup>
  - Low COF for dissection 'tacking'

Source: BIOFLEX PEACE (interim). Lichtenberg M. Presented at LINC 2017. 1) 4EVER Bosiers M. JEVT 2013;20:746-756; 2) PEACE Lichtenberg M. JEVT, 2014, 21:373-380; 3) Laird JR, Katzen BT, Scheinert D, et al., Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve month results from the RESILIENT randomized trial. Circ Cardiovasc Interv. 2010;3:267-276; 4) Matsumura JS, Yamanouchi D, Goldstein JA, Pollock CW, Bosiers M, Schultz GA, Scheinert D, Rocha-Singh KJ. The United States Study for Evaluating Endovascular Treatments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the Protégé EverFlex Nitinol Stent System II (DURABILITY II). J Vasc Surg. 2013 Jul;58(1):73-83.e1. doi: 10.1016/j.jvs.2012.12.066. Epub 2013 May 2. 5) Bosiers M, Torsello G, Gissler HM, et al., Nitinol stent implantation in long superficial femoral artery lesions: 12-months results of the DURABILITY I study. J Endovasc Ther. 2009;16:261-269.

# Thin strut, low COF SE stents represent a promising clinical option as a standalone or combination solution



## Properties of an ideal SFA stent

- Low **Chronic Outward Force (COF)**
- High multidirectional flexibility
- Sufficient Radial Resistive Force (RRF)
- Sufficient Crush Resistance (CR)
- Accurate deployment



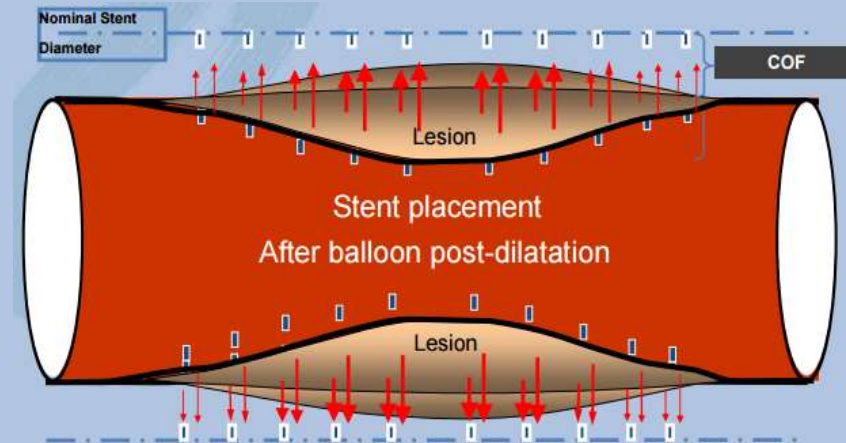
**RRF**  
(resistance to **concentric** compression)

**CR**  
(resistance to **eccentric** compression)



## COF in summary

- Chronic force exerted by a nitinol stent on vessel wall
- COF depends on:
  - Oversizing
  - Stent material and design
  - Irregularities in the lesion

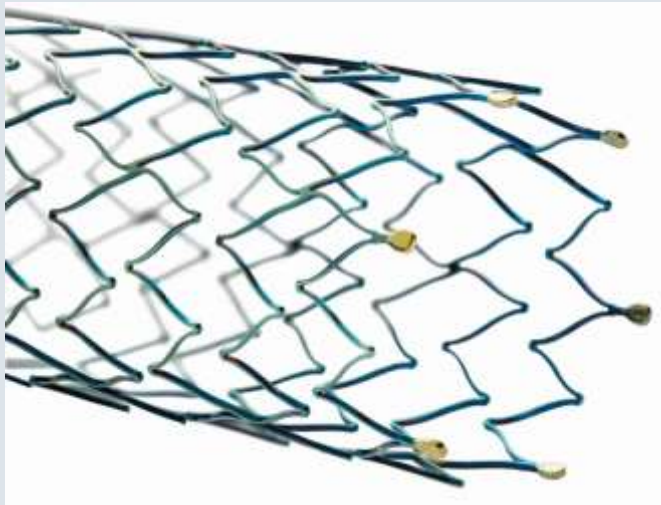


# BIOTRONIK Pulsar-18 SE Stent

## Pulsar-18 Specifications

### Pulsar-18 specifications

- 0.018" OTW Nitinol Stent
- $\varnothing$ : 4.0-5.0-6.0-7.0 mm
- **Strut thickness 140 $\mu$ m**
- L: 30-40-60-80-100-120-150-170mm
- proBIO coated (Silicon Carbide)
- **4F** Introducer Sheath compatible



**Thin Struts**



**Low COF**  
(Chronic Outward Force)

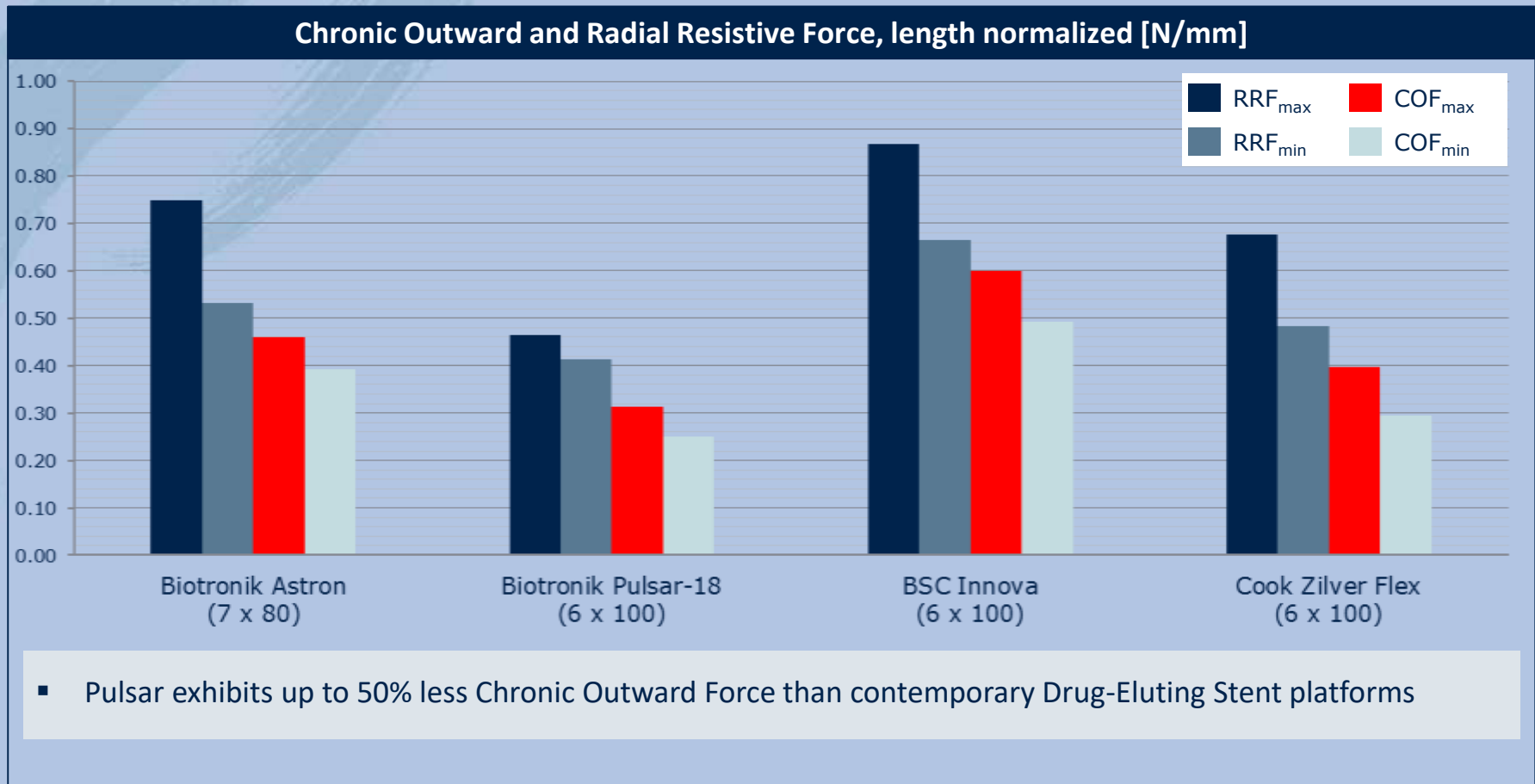


**Clinically Proven**

# Thin strut, low COF SE stents represent a promising clinical option as a standalone or combination solution



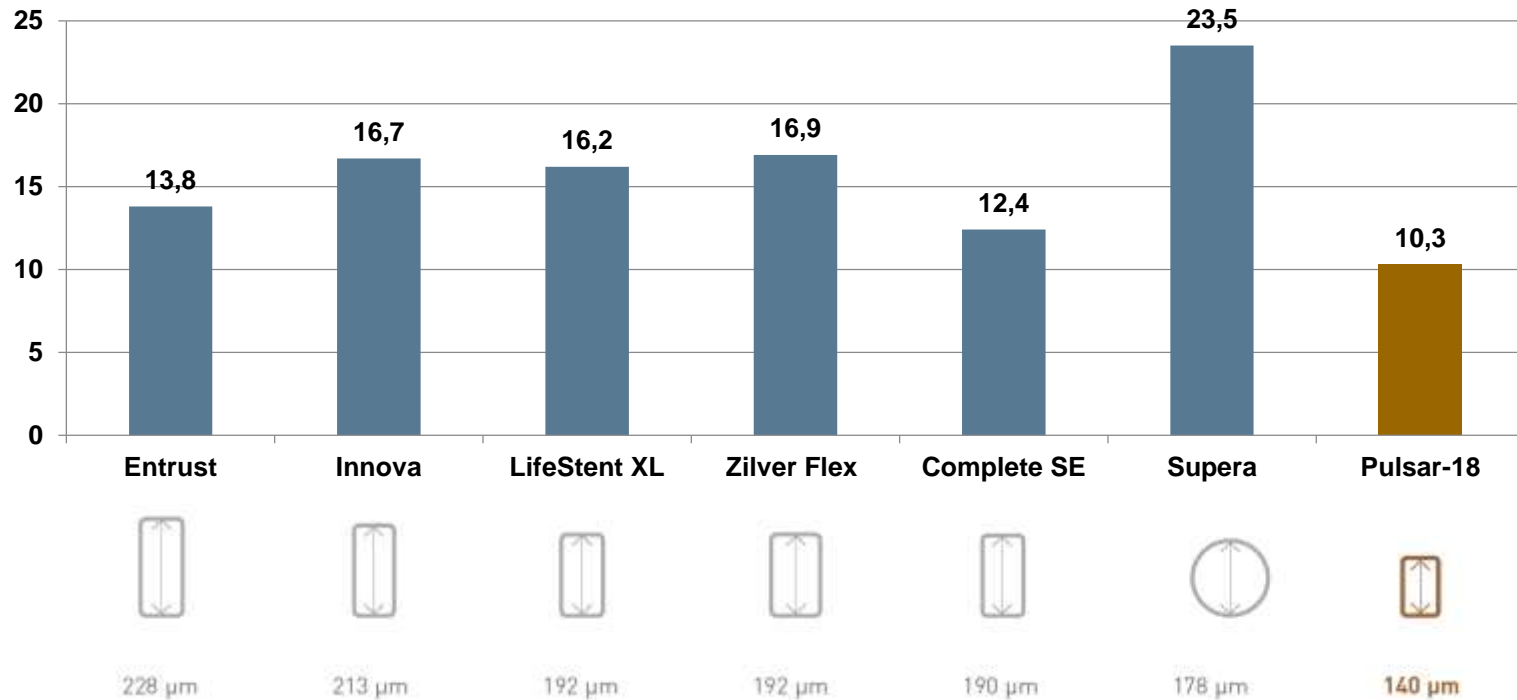
## Different Stents, different forces on the vessel



# Pulsar-18 has the thinnest struts and lowest outer surface area of all FDA approved SFA stents



Calculated stent outer surface area (stents fully open) %



- Pulsar has the lowest metal to artery ratio (outer surface area ratio) of modern SE Stents
- Thinner struts have been shown to have a lower restenosis rate<sup>2</sup>.



# Could low-COF, thin strut stents be a good match for DCB?



Current Practice

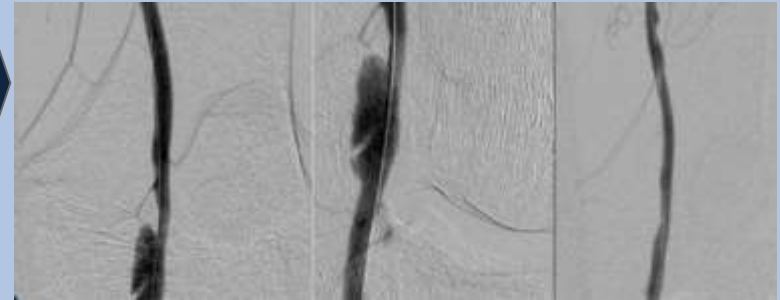
High COF Stents  
Stent oversizing  
Atherectomy & DCB



Weaken/remove IEL  
Aneurysmal changes  
Vessel Injury  
Inflammatory response



Aneurysms reported in 7% of DAART patients<sup>1,2</sup>



Vascular Mimetic  
Implant & DCB



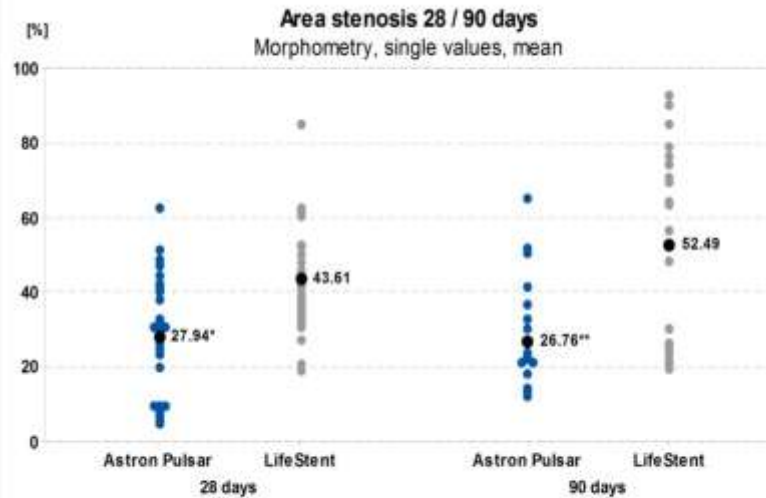
High metal-artery ratio  
'Trapped' PTX? (no washout)

Pulsar BMS

Low COF  
Thin Struts



Lower injury score vs. high COF stent<sup>3</sup>  
Less inflammation<sup>3</sup>  
Lower metal-artery ratio<sup>3</sup>  
Less risk of exacerbating cytotoxic effects of PTX?

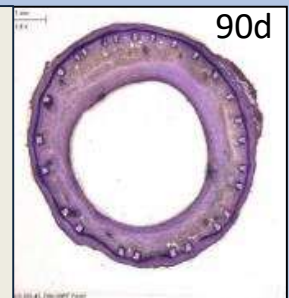


\* sign. diff. vs. LifeStent (p-value = 0.0001, mean (t-test))  
\*\* sign. diff. vs. LifeStent (p-value < 0.0001, median (Mann-Whitney Rank Sum))  
Sample number 28 days: Astron Pulsar = 28; LifeStent = 28  
Sample number 90 days: Astron Pulsar = 21; LifeStent = 21

Astron Pulsar



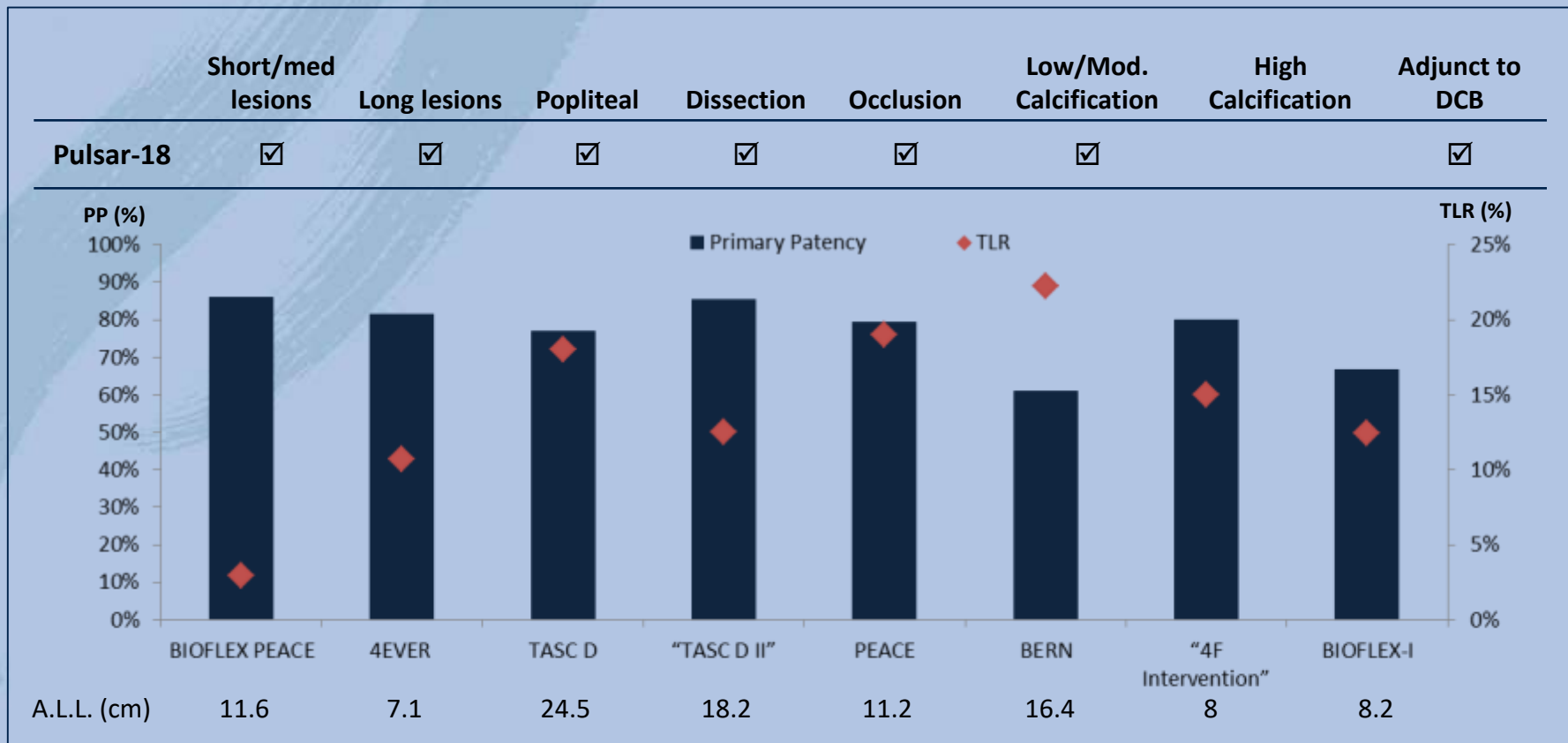
LifeStent







# Pulsar-18 clinical results



- Pulsar has demonstrated consistent clinical performance in several clinical studies.
- Results are consistent across a range of lesion lengths.

# Summary

Bare-metal SE stents play an important role in SFA therapy as a proven standalone or adjunctive option



Thin-strut, low COF Stents appear to reduce vessel injury and inflammatory response based on preclinical and clinical evidence.



Thin strut, low COF stents as an adjunct to DCB may avoid exacerbation of vessel injury associated with a weakened internal elastic lamina



SE stents must be uniquely clinically proven as standalone or adjunctive options- no class effect exists.



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