Dr. Lualdi's Technologies

1- The "Passkey"

2- The "Carrier"

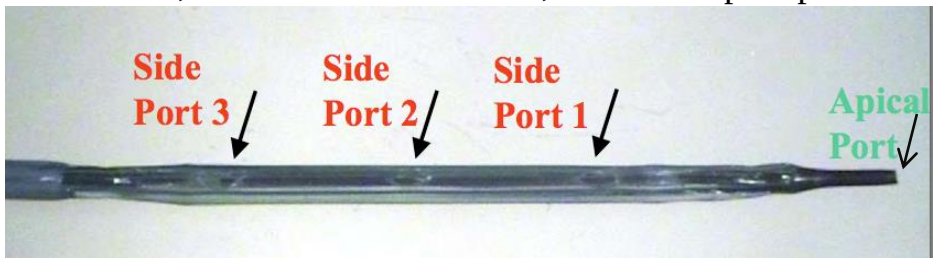
3- The "Hinge-Wire"

4- the "MiniPasskey"

1 -- The “Passkey”

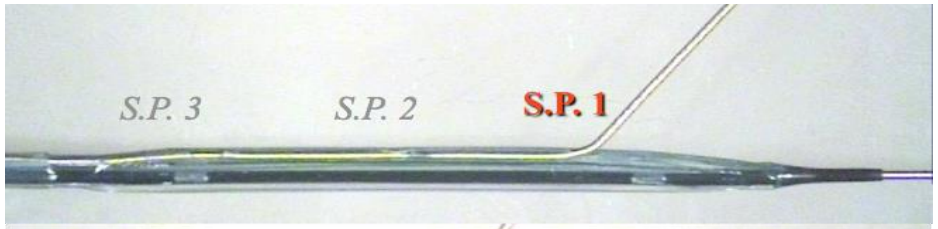
DESIGN CHARACTERISTICS:

- The “core “of the technologies is a unique Stent Delivery System (SDS): the “**Passkey**”. It consist in a simple "*rapid-exchange*" balloon, 6F compatible. Differently from all other common balloons it has a second ancillary Guide-Wire lumen, within the balloon wall, with multiple optional side ports . These simple features makes this product unique



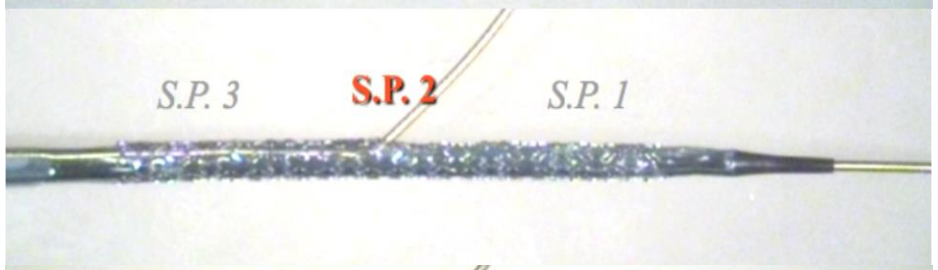
A folded sample of the Passkey.

Note the multiple side holes of the second lumen, created in the balloon wall

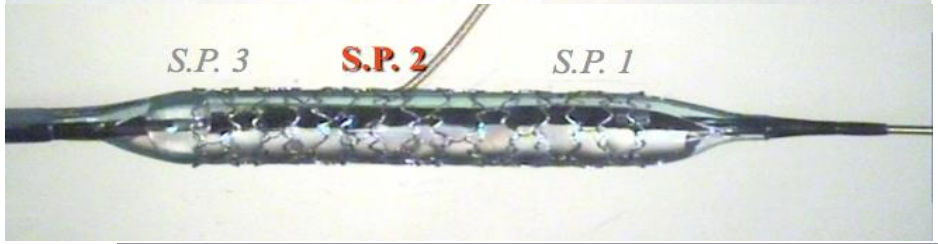


A folded sample of the Passkey, with a first GW, for the Main Branch of the BL, is inserted at the balloon tip, into the central GW lumen.

A second GW, for the Side Branch of the BL, is inserted into one of the 3 holes of the second lumen created within the balloon wall.



A folded sample of the Passkey, with a stent crimped on it, and ready to be advanced on both GWs and to be positioned in a BL



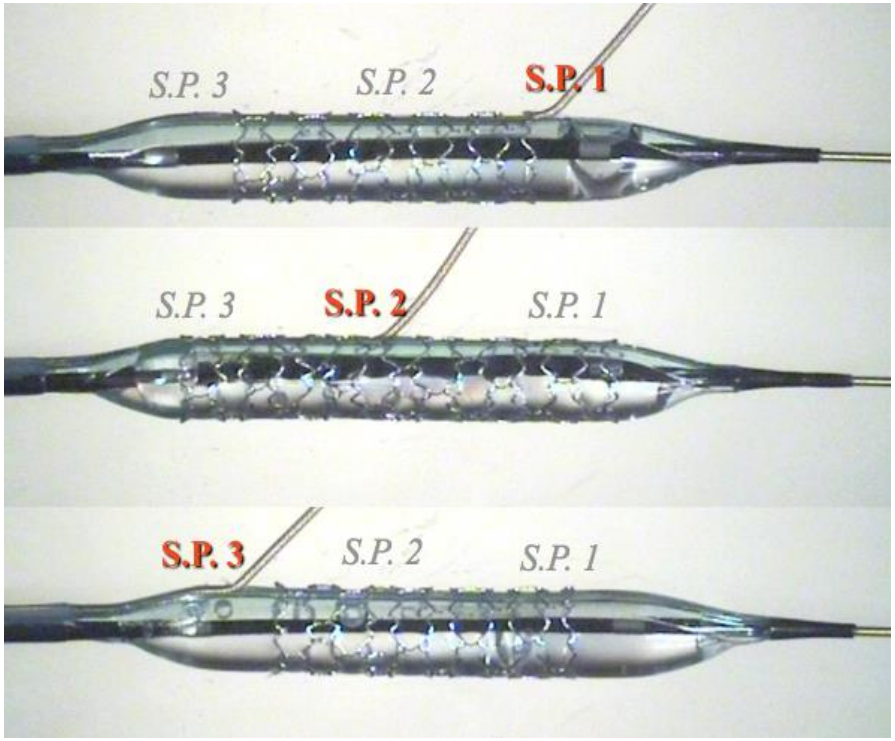
Tha Passkey is now inflated and the stent normally expanded.

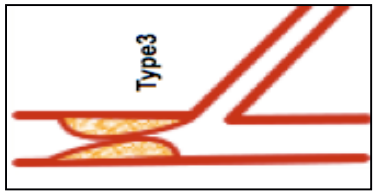
Note the ancillary GW out of the Passky and across a stent cell, allowing the continuous access to the side brach, even after the stent deployment in a BL .

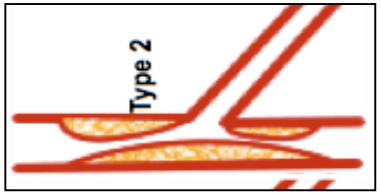
1 -- The “Passkey”

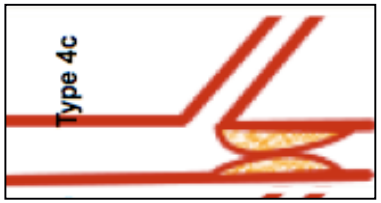
◆The second GW, for the Side Branch of the BL, could be inserted most conveniently into one of the 3 holes of the second lumen created within the balloon wall.

◆The chance to chose one of the holes along the balloon body at his convenience, allows the operator to deploy the stent. proximally, distally or just over the Side Branch origin









◆ Conceived for the Bifurcation Lesions (BL) treatment, the Passkey is the only BL "dedicated" double access SDS (to main branch and side branch) utilizing a single balloon with circular cross section, as any all common SDS.

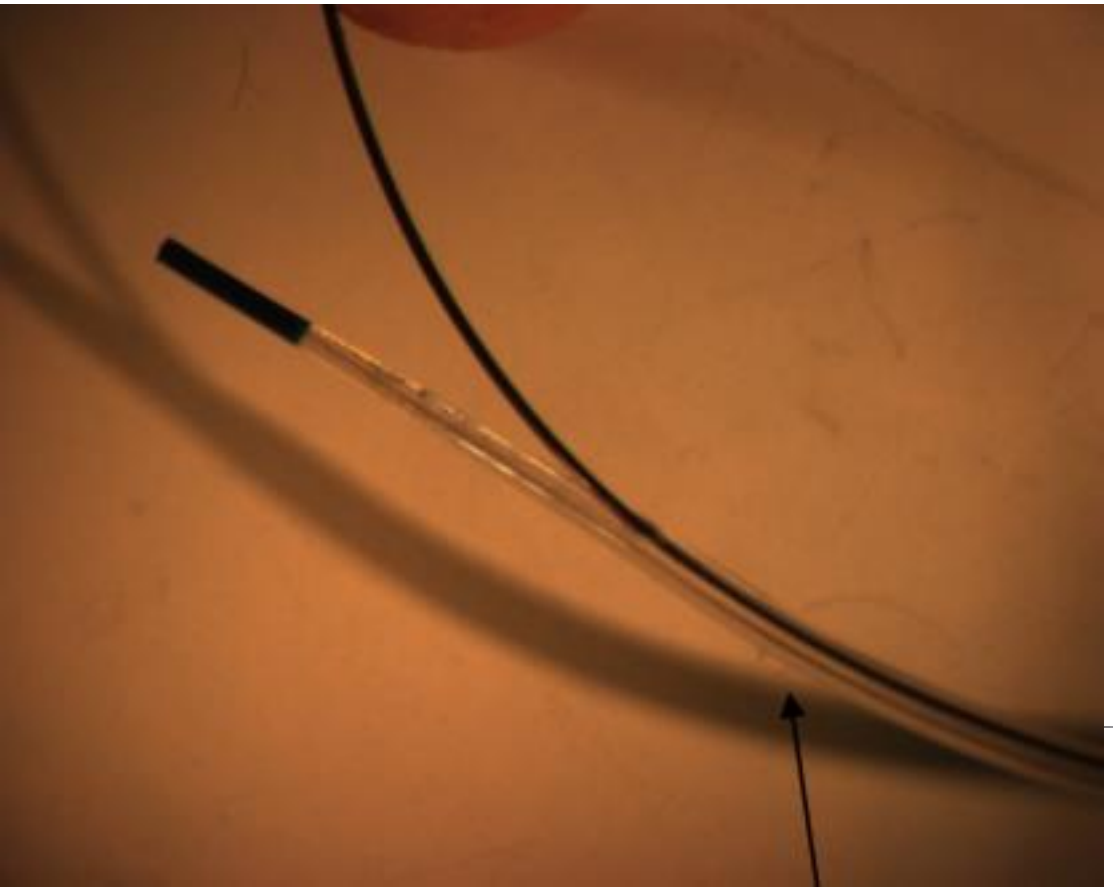
The feature, of consisting in a single balloon , differentiates it from all other BL "dedicated " devices that are are “binary” systems : 2 balloons or a balloon + an addidional hypotube for the II° GuideWire. Consequently, they are difficult to be managed, as they are bulky and have a flexibility limited on a single axis, and can fit only some BL types

2 -- The Guide-Wire "Carrier"

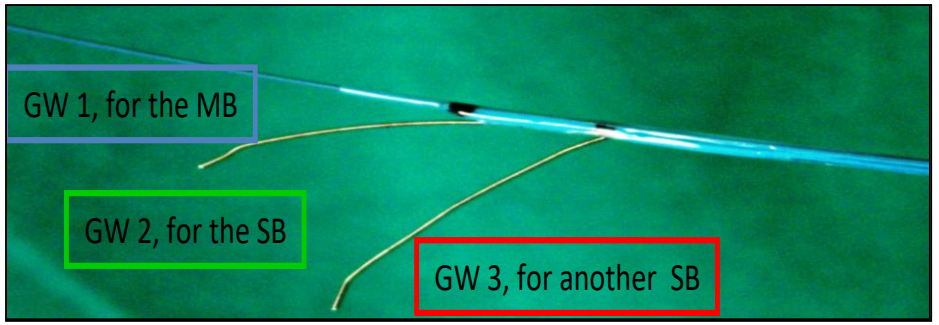
DESIGN CHARACTERISTICS:

- I**the Guide-Wire "Carrier"**, a simple, short, multiplelumen, rapid-exchange catheter. Conceived to facilitate and to make safer the procedures requiring the use of multiple GuideWires,

Its scope is to enable an easy and quick deployment, of additional Guide-Wires, avoiding the frequent GW troubles, observed during their handling, and the difficulties to reach the side branch



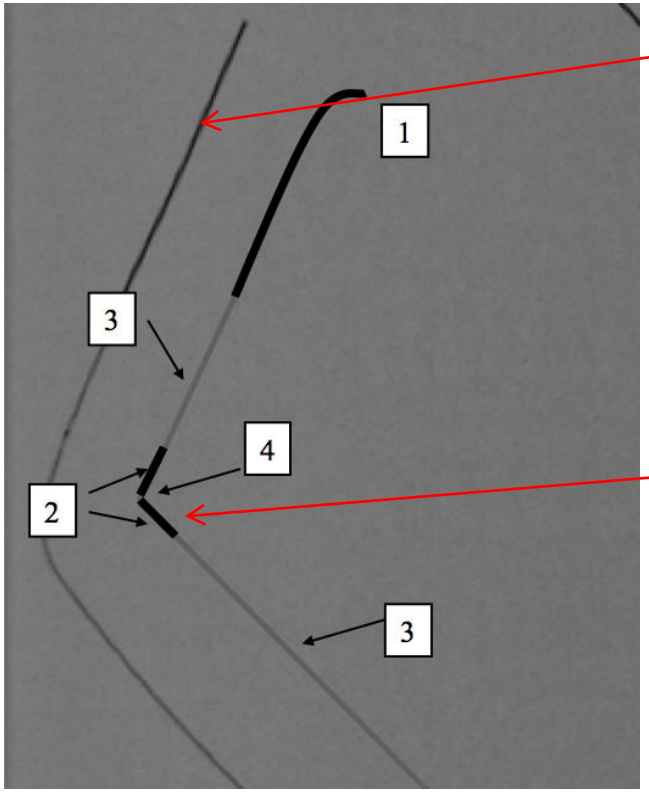
This sample, in this picture, has 3 lumens where the apical one is used to advance the device, while in the other lumens must be loaded the GuideWires to be delivered by means of the "Carrier".



3 -- The “Hinge-Wire”

DESIGN CHARACTERISTICS:

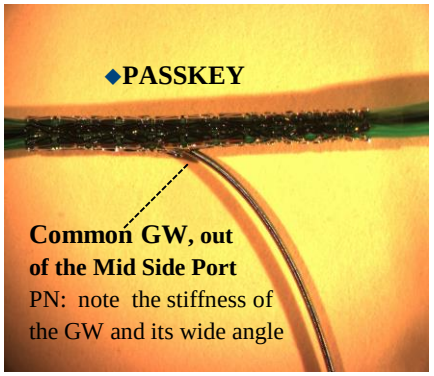
- The “**Hinge-Wire**” is a unique GuideWire that can be bent 90˚ , easily, in a specific point, due to the presence of a hinge that allows the GW to be flexible without recurring to forces which could oppose or hinder the advancement and positioning of the SDSs



Common GuideWire .

Its bending requires forces which push it against the vessels wall.

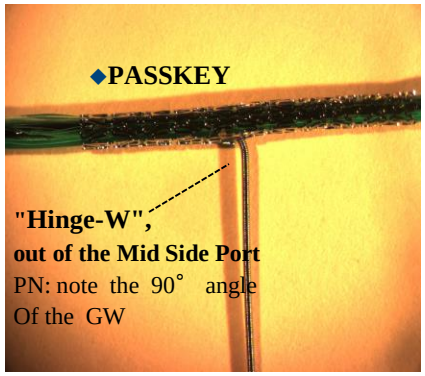
So the GW pushes the **Passkey** against the vessel wall, causing friction and disadvantaging the favorable positioning of the stent



The Hinge-Wire .

Its easy bending doesn’t require forces and it is naturally positioned in the middle of the lumen.

So, the **Passkey** can be advanced and positioned more easily and conveniently rotated with less fricion.



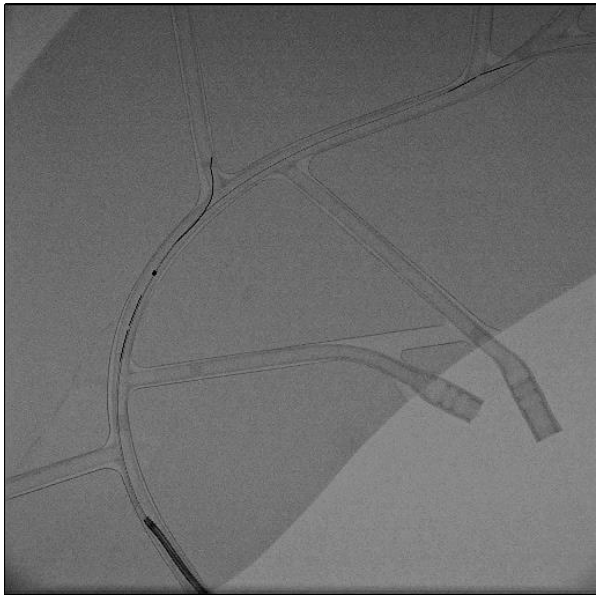
HOW TO USE THE "HINGE-WIRE":

- Conceived to be used as ancillary GW, for the Side Branch in BLs treatment with "dedicated" SDSs provided with a double GW lumen.
- Ideal for a combined use with the Passkey, it complete the solution for the treatment of all complex lesions, along with he "Carrier".
- Thanks to its flexibility, promotes the correct stent positioning.

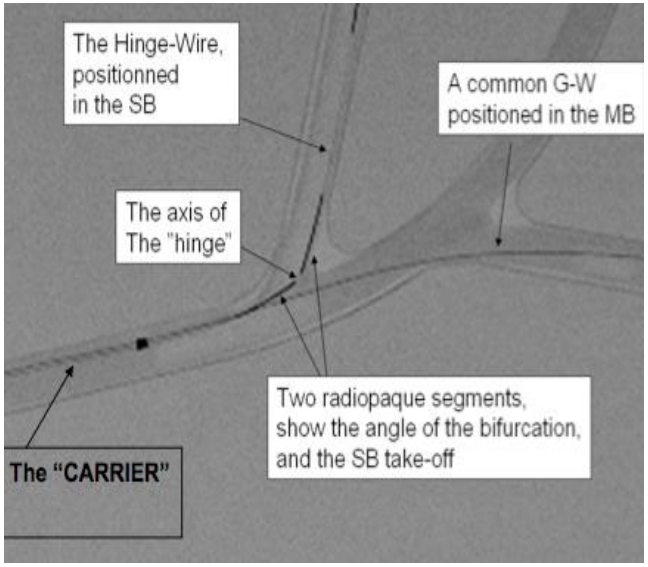
2 +3 - The Guide-Wire “Carrier”+“Hinge-Wire”

HOW TO USE THE "CARRIER” AND “ THA HINGE-wIRE”:

- After its positioning in the main branch, the first GW is inserted in the apical lumen of the G-W "Carrier". This latter, with a second GW previously inserted and fixed in the additional lumen, is then advanced up to the lesion. After the convenient positioning of the second GW, the "Carrier" is drawn off, leaving the two GWs perfectly parallel and ready for a safe advancement of a SDS



click on the picture for animation



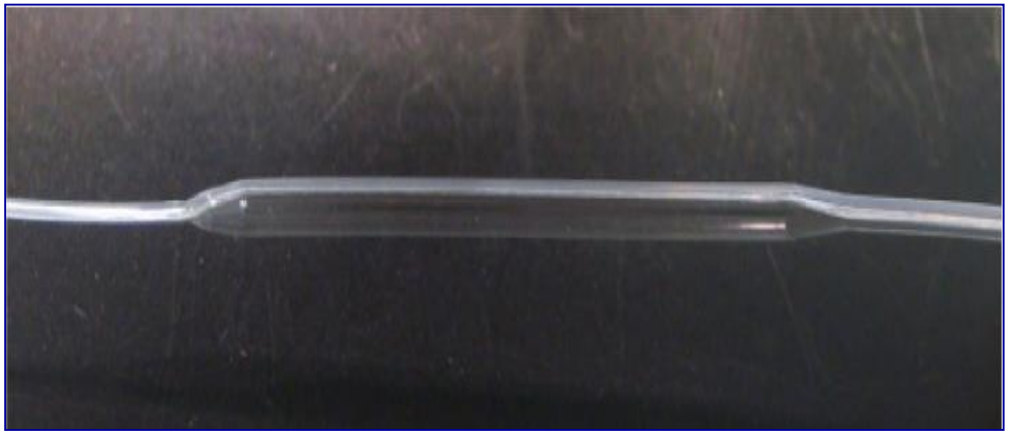
ADVANTAGES OF THE "CARRIER":

- Unique on the market, very simple to handle and extremely useful device, allows to shorten the procedures time and to avoid complications.

4 -- The "Mini-Passkey"

DESIGN CHARACTERISTICS:

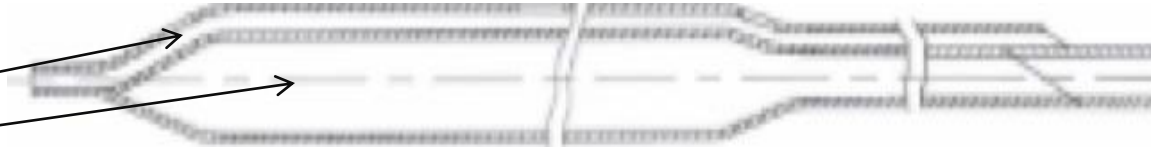
- The "**Mini-Passkey**" is a micro-balloon without the inner tube for the GW, because it runs in the balloon wall
  - This should allows to manufacture extremely thin balloons which will be particularly indicated for angioplasty of the distal and small vessels, in any vascular territory



First extrusion of a 30-2.0 mm MiniPasskey.
Please, note the absence of a inner tube for the Guide Wire.
This allows to reduce the diameters of the balloon when folded.

Oversimplified design, cheaper manufacturing

MiniPasskey:
GW passageway in the balloon wall
No inner tube



Conventional balloon:
Inner tube for the GW passageway