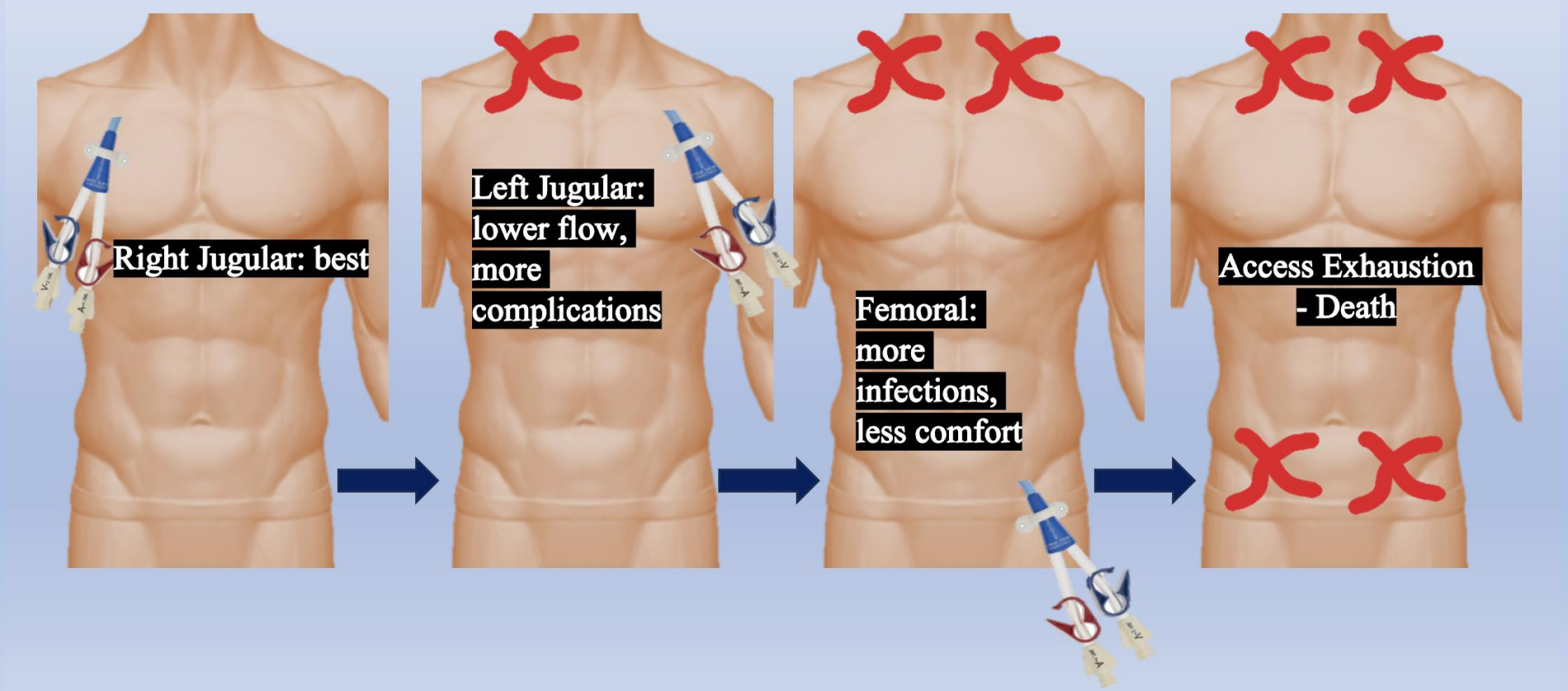
Access Preservation Catheters: New Medical Devices for an Unmet Need

Preserving access, extending life.

Catheters Play a Central Role In Hemodialysis (HD) Access

Roughly 80% of patients start HD using an implanted catheter, almost always via the most effective approach, the right internal jugular vein. While patients are then converted to arm access (fistulas and grafts), catheters remain necessary when fistulas and grafts fail.

A major problem: catheters can injure the very veins they pass through. When patients need more than 1 catheter over their dialysis lifetime (over 70%), there can be a cascade of access loss:



Access Loss: a Critical Challenge in Hemodialysis

Patients affected:

~ 240,000/yr

Rely on a Left Jugular Catheter

Right jugular pathway occluded. Lower flow, more complications.

~ 60,000/yr

Endure long-term Groin Access

Upper body vein pathways occluded. Uncomfortable and prone to infections.

12-15,000/yr
15,000/yr

Die from Access Exhaustion

All vein pathways occluded

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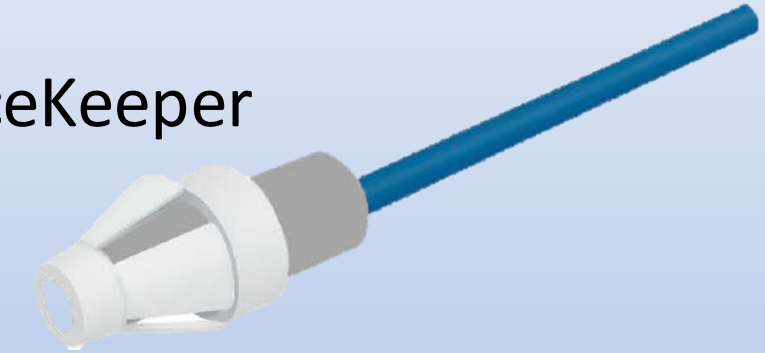
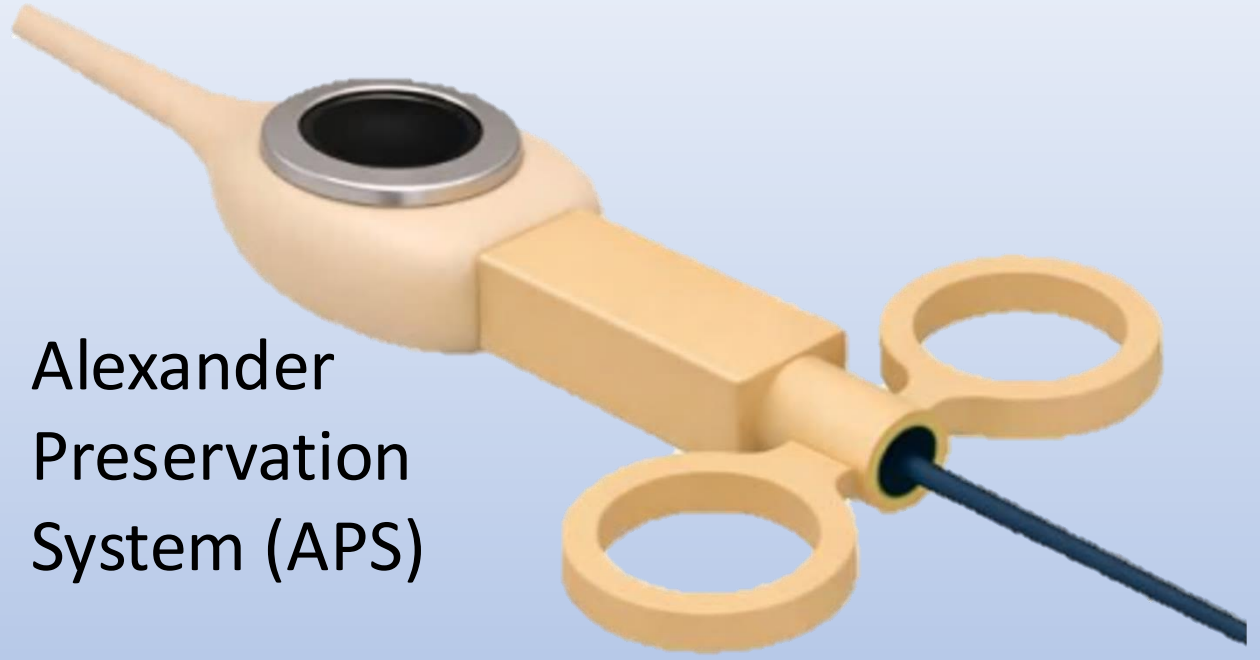
Current Solutions

Solution: Access Preservation Catheters (APCs)

PlaceKeeper



Alexander Preservation System (APS)

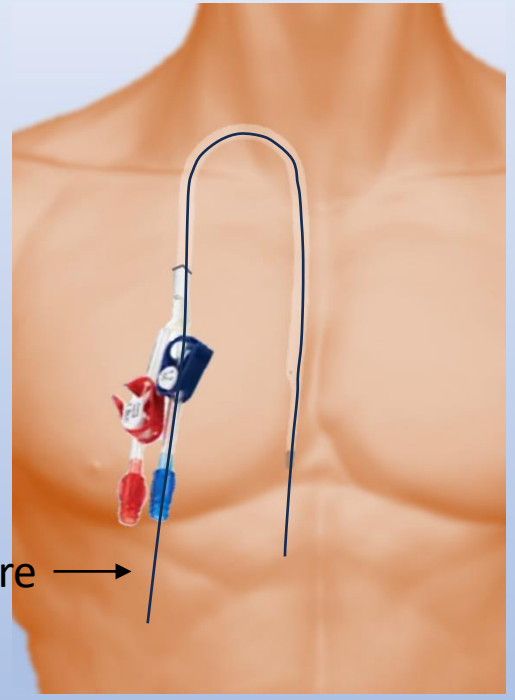


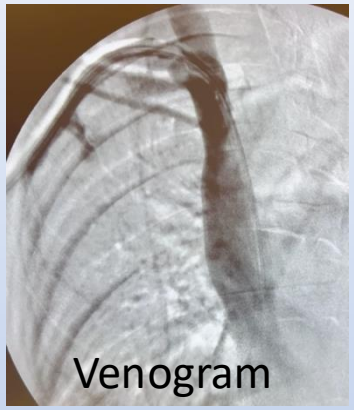
Patients: fewer failed procedures, fewer catheters in poor locations, fewer needle sticks, and protection against access exhaustion.

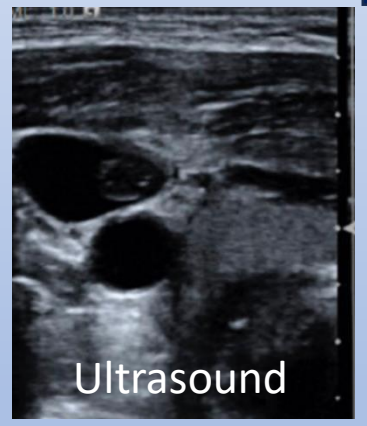
Providers: simplify re-access and make long-term planning more predictable.

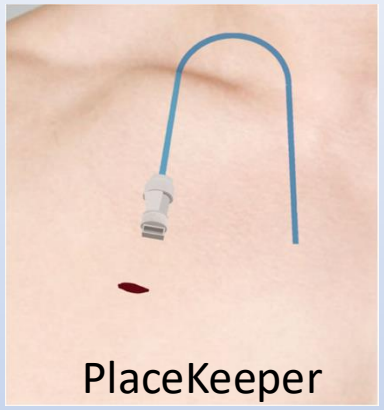
The healthcare system: reduce complications and lessen financial burden by avoiding complex and costly access procedures.

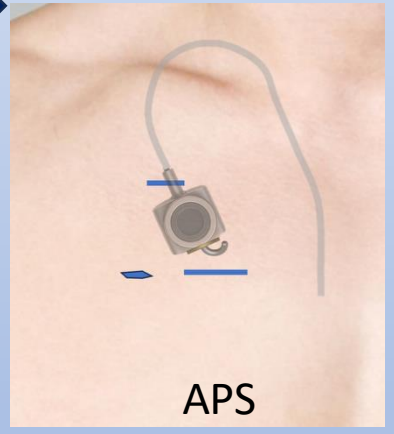
Exchange Procedures to Preserve Access

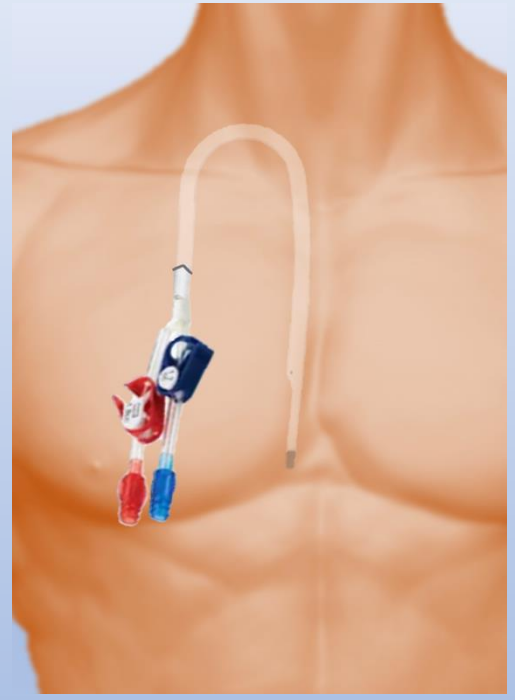








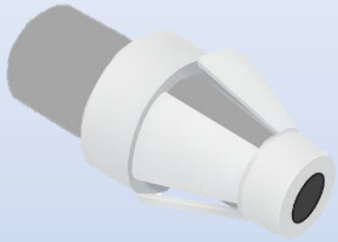




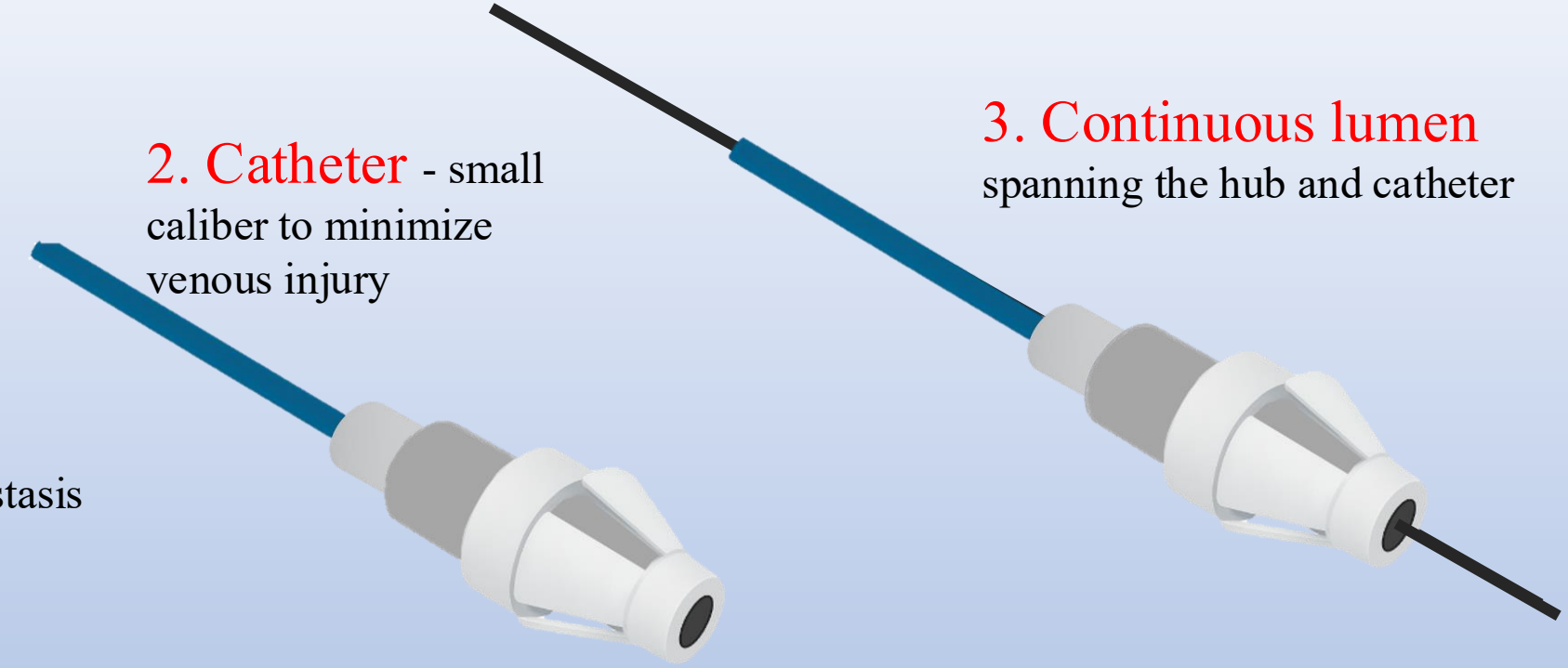
At the time of HD catheter removal, the operator checks for pathway injury using a venogram and duplex ultrasound. If there is no significant injury, the catheter is simply removed. If there is injury, the catheter is exchanged for an APC.

The next time a patient needs a catheter, the reverse is done: the APC is exchanged over a wire for the HD catheter

APC – Design Components



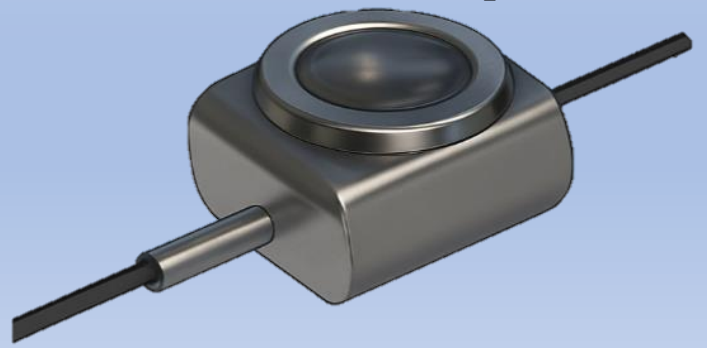
1. Hub designed for hemostasis and secure fixation

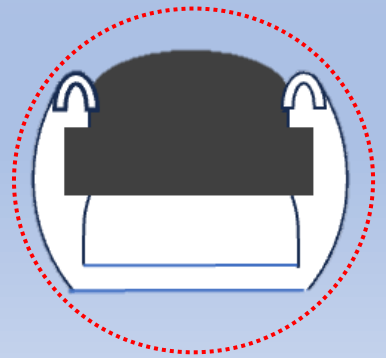


2. Catheter - small caliber to minimize venous injury

3. Continuous lumen spanning the hub and catheter

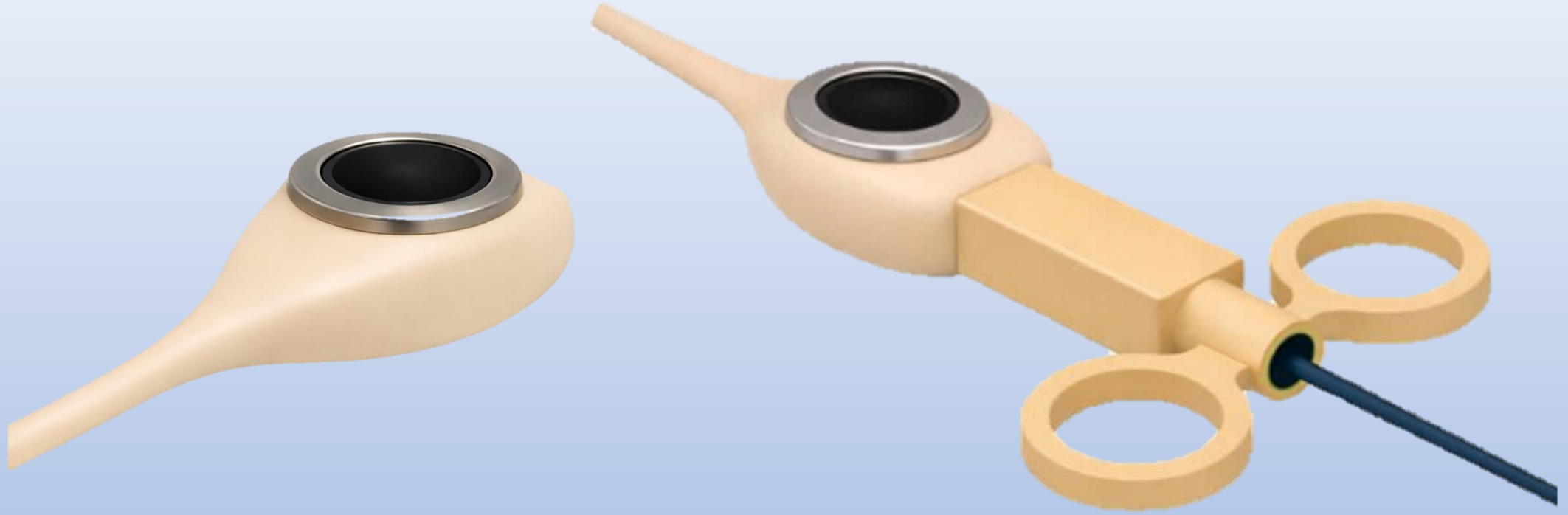
4. Rounded contours for easy implantation and exchange





Each APC is fully internal and comprises a subcutaneous hub, a narrow-caliber catheter, a continuous lumen spanning the hub and catheter, and rounded hub contours.

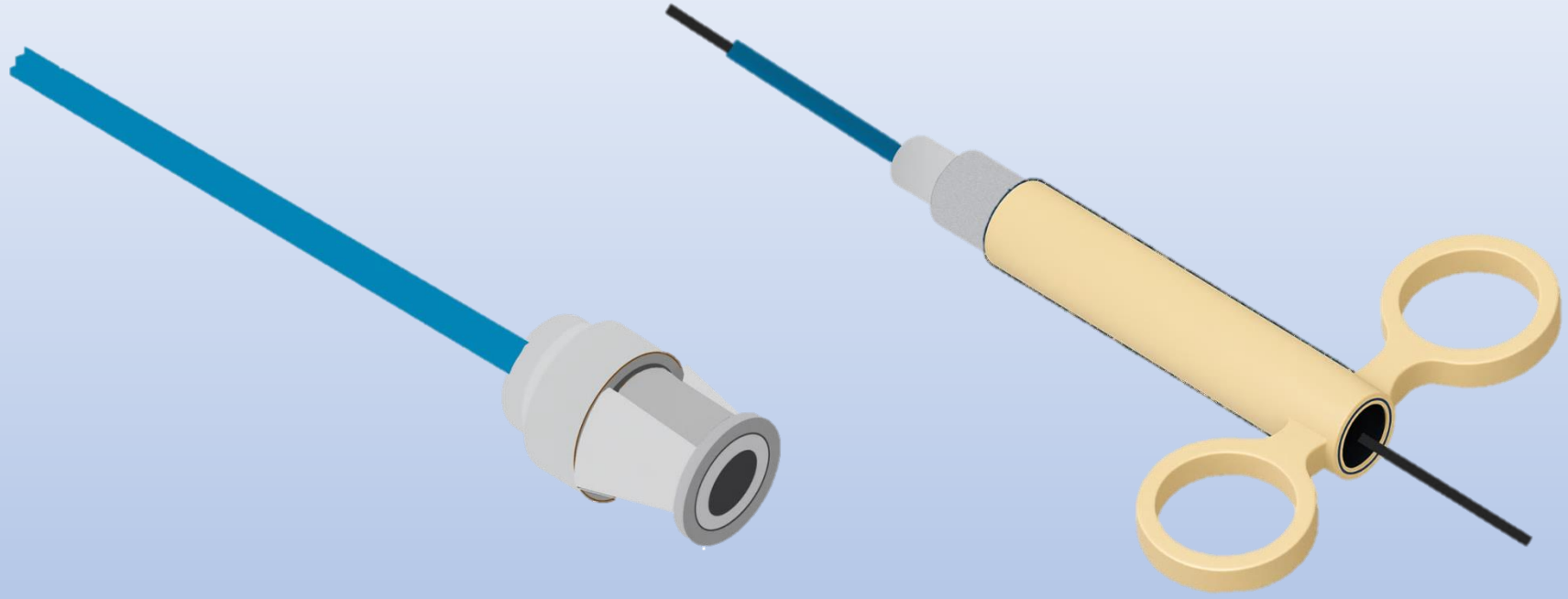
Lead Product: Alexander Preservation System (APS)



The APS, our lead product, has a portacath-style hub. It combines the long-term functionality of a portacath with the unique exchangeability of the APC system. The APS not only protects central venous pathways but also reduces reliance on peripheral IVs and PICCs. This helps preserve peripheral veins for fistulas and grafts.

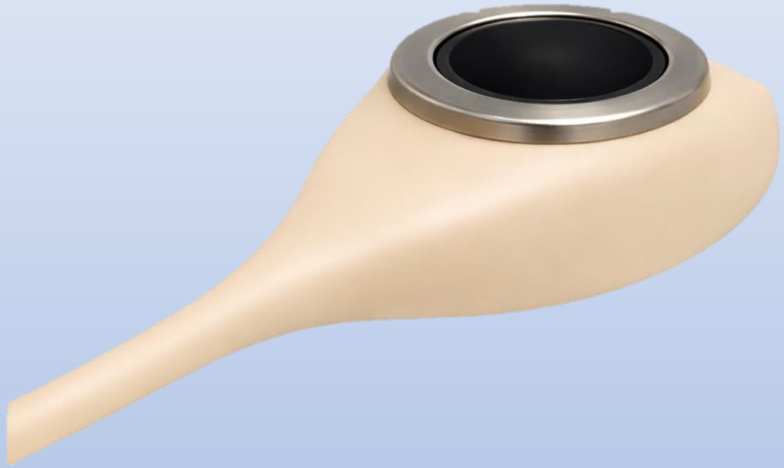
In short, the APS functions as a familiar device, a portacath, but it is purpose-built for easy implantation and catheter exchanges. That distinction is critical to meet the long-term needs of dialysis patients.

Pipeline Product: PlaceKeeper

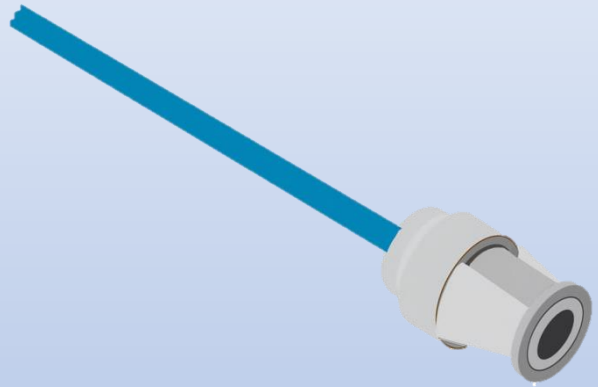


Alongside the APS, we are developing the PlaceKeeper — a simpler, faster variant of an APC. Its advantage is speed and simplicity: it can be placed in under a minute, providing immediate pathway preservation. But it faces a more extensive regulatory approval process through the De Novo pathway. Safety and efficacy still need to be demonstrated.

Regulatory & Development Strategy



Well-established 510(k) FDA pathway.
Standard portacath as predicate.



Pipeline. De Novo FDA pathway and clinical trials.

Staged strategy: APS first, PlaceKeeper second.

APS Total Addressable Market (TAM)

Clinical Scenarios	TAM		Outcomes	Reasonable Practice?
	US	Global		
1. Current practice: no APCs.	$0	$0	Exhaustion death, groin access, LJ access, many peripheral IVs.	In a few years, no.
2. Implant APC after every catheter removal – maximum potential TAM.	$340M	$2B	No exhaustion death, no groin access, no LJ, no peripheral IVs.	Too expensive, too many CRBSIs.
3. Implant APC after every left jugular catheter (LJ) removal. Permit the patient to lose the RJ but always preserve the surviving LJ. Frequency = 20%. Prevalence = 10%.	$36M	$216M	No exhaustion death, no groin access. LJ access. Some peripheral IVs.	Reasonable, but not as good clinically as preserving the RJ.
4. Screen all RJ catheter removals; implant those at risk for occlusion. Probability of access loss/removal = 5%. Screening errs on the side of preventing RJ loss, so about 10% of RJ removals receive APCs. Prevalence = 14%.	$55M	$330M	No exhaustion death, no groin access, no LJ access. Some peripheral IVs.	Reasonable, and very good clinical outcome.

Growth – PlaceKeeper Addition and an Expanding ESRD Population

PlaceKeeper TAM

- Complementary to APS, since quicker and easier to implant compared to the APS
- Forecasted use: first implant a PlaceKeeper, then convert it to an APS days or weeks later.
- Clinical trials may support the PlaceKeeper as a long-term solution.
- We forecast a 30-40% boost in revenues based on the addition of the PlaceKeeper to the portfolio 2-3 years after APS market entry.

Growth in ESRD Population

- Forecasted 2-4% growth in the ESRD market, reaching close to 1M ESRD patients in the US and 5M globally by 2035
- APC TAM will scale with growth.

Market Competition: The Central Access Catheter Landscape

No current device on the market is designed specifically for access preservation in ESRD patients.

Current related venous access devices include HD catheters and portacaths. In theory, these existing devices could be used for access preservation, but there are clear liabilities.

HD Catheter Market

Current Market: $400M US, $1.6B global

Company	Product	Market Position
BD / Bard	PowerFlow	40%
Medtronic	Palindrome	25%
AngioDynamics	BioFlo	15%
Teleflex	Arrow NextGen	10%

Vs APC For Access Preservation?

1. External portion, so
   - Higher infection risk.
   - Higher death risk.
   - Limits bathing or any activity that could cause infection.
   - Limits clothing and other cosmetic choices
2. Large caliber catheter - increases risk of further injury to central veins.

Clinical Practice: Standard HD catheters are maintained indefinitely only as a last resort.

Portacath Market

Current Market: $200M US, $500M global

Company	Product	Market Position
BD / Bard	PowerPort	46%
Angiodynamics	SmartPort	25%
ICU Medical	Port-A-Cath	
B Braun	Celsite	

Vs APC For Access Preservation?

- More steps to insert or exchange.
- Harder to manage infections
- Larger incision.
- Harder to free from a subcutaneous pocket for exchange.

Clinical Practice: Done only infrequently due to multiple steps and infection management concerns.

“Placeholders”: Ad Hoc Sutured Catheter Fragments

Vs APC For Access Preservation?

Not a Manufactured Product

Not a solution for an access preservation program.

Clinical Practice: Done rarely and only in patients whom the operator knows well from prior access loss issues.

Clinical Validation Plan

APS

PlaceKeeper

This staged validation ensures both devices are proven for their intended roles — APS as the durable standard, PlaceKeeper as the short-term bridge.”

APCs Change Practices. Will That Happen?

- Current standard: no evaluation, pull the catheter.
- New standard: screen patient (history, duplex, venogram) then place APC if indicated.

Adoption Issues	Medical Advisory Board Answer
Is access loss a significant clinical problem worth solving?	**Yes**
Are APC placements technically straightforward?	**Yes**
Will access preservation appeal to clinical nephrologists?	**Yes**

APCs Will Be Adopted

Development Partners

Medical Advisory Board

Nicholas Inston, PhD, FRCS, National Clinical Lead, Organ Utilisation (Kidneys) – NHS Blood and Transplant (UK)

Joachim Ix, MD, Chief of Nephrology, University of California, San Diego

Timmy Lee, MD, Chief of Nephrology, University of Alabama, Birmingham

Rishi Razdan, MD, Head Peer Review, Azura/Fresenius Vascular Care

Murat Sor, MD, Chief Medical Officer, Azura/Fresenius Vascular Care

1 more?

Business Development

Joseph Garner, PhD
**[choose organization]

One more?

To execute this plan, we are partnering with leaders in dialysis access. These partners will serve as clinical champions, helping design studies, generate peer-reviewed evidence, and accelerate adoption.

Don’t accept central access loss, prevent it.

- APS, a near-term, low-risk product on a predictable regulatory path.
- PlaceKeeper, a pipeline innovation that adds speed and simplicity.
- Together, a system to safeguard the lifeline of every dialysis patient.
  - Limit or prevent access exhaustion.
  - Limit or prevent long-term femoral access.
  - Limit left jugular access.
- Clear roadmap, evidence-driven validation, partnered with leaders in dialysis access.

APD VENOUS ACCESS FOR LIFE™
ACCESS PRESERVATION DEVICES