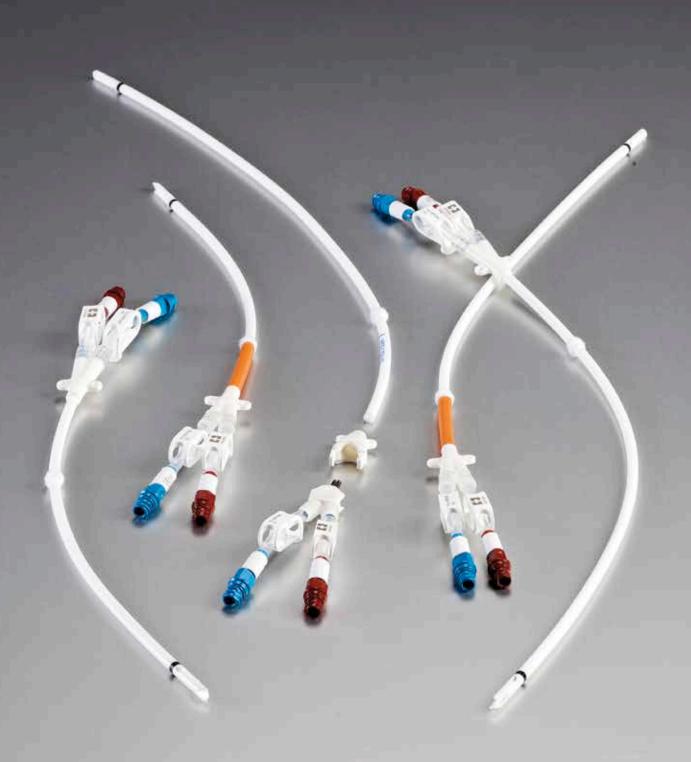
# DIALYSIS IS CRITICAL. PRESERVING ACCESS IS ESSENTIAL.

Palindrome™ Precision Chronic Dialysis Catheter Family









#### A LEADER IN PATIENT CARE

Performance. Confidence. Our Palindrome™ Precision family of chronic hemodialysis catheters features unique design, innovative coatings, precision tip technology — and a legacy you can count on. Internal testing supports the following features unique to the Palindrome family of catheters:

#### Palindrome™ Precision symmetric tip dialysis catheter

The symmetric tip with marker band technology and laser-cut side slots increases tip visualization — reducing recirculation. It incorporates a design that promotes adequate flow over the duration of use.<sup>1-3</sup>

# Palindrome™ Precision H-heparin coated dialysis catheter

Internal testing shows that the noneluting heparin coating decreases the likelihood of platelet adhesion and inhibits fibrin sheath propagation.4

#### Palindrome™ Precision SI-silver ion antimicrobial dialysis catheter

Internal testing shows that the silver ion sleeve reduces colonization on the catheter surface against a broad spectrum of bacteria for at least 15 days, if not longer depending on the organism.5

# Palindrome™ Precision HSI-heparin coated and silver ion antimicrobial dialysis catheter

Heparin coating and a silver ion sleeve are incorporated into the dialysis catheter — which, internal testing shows, reduces the likelihood of platelet adhesion and colonization against a broad spectrum of bacteria for at least 15 days, if not longer depending on the organism.<sup>4</sup>

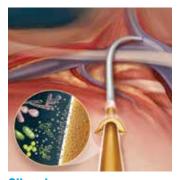
# Palindrome™ Precision RT–reverse-tunneled dialysis catheter

Reverse-tunneled catheter tip facilitates precise tip and cuff placement using the retrograde tunnel technique.





Symmetric tip Heparin coating



Silver ion antimicrobial sleeve



Reverse-tunneled

# **Palindrome™ Precision Symmetric Tip Dialysis Catheter**

#### **Maximum Flow Rates**

The Palindrome™ Precision dialysis catheter — with its internal lumen design, 14.5Fr diameter, and durable Carbothane™ material — is able to consistently deliver high flow rates.<sup>6</sup>

High tensile strength material and internal lumen design optimize inner diameter integrity without compromising flexibility or kink resistance.

#### **Dependable Patency**

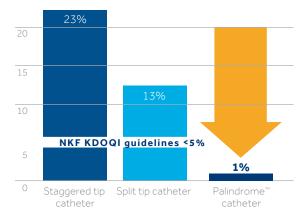
The unique symmetric tip design and laser-cut side slots promote catheter patency $^{7}$ :

 Laser-cut side slot surfaces are smooth which helps discourage platelet adhesion and minimize debris attachment.<sup>7</sup>

#### **Reduces Recirculation**

Based on a study using a swine model, the Palindrome™ Precision catheter demonstrated reduced recirculation rates in accordance with NKF KDOQI guidelines when in forward or reverse flow²:

- Studies show that dialysis lines are frequently reversed.<sup>1</sup>
- When lines are reversed, blood recirculation increases.8



Staggered catheters were MAHURKAR<sup>TH</sup> Maxid non-side hole catheters. Split tip catheters were Medcomp Split Cath<sup>TH</sup> catheters.<sup>2</sup>

# **Palindrome™ Precision Symmetric Tip Dialysis Catheter**

### **Tal VenaTrac™ Insertion Stylets**

Over-the-wire insertion stylets allow for an over-the-wire insertion technique. This creates a staggered tip effect for easier<sup>9</sup> left-sided or subclavian catheter placements and eliminates the need to use a pull-apart sheath.

In a retrospective review of catheter insertions and sheath insertion comparison, this unique design:

- Reduces blood loss
- Promotes over-the-wire catheter exchanges
- Allows for sheathless initial catheter insertions

#### **Reduced Intervention Rate**

In a case-controlled study, the Palindrome<sup>TM</sup> SI-silver ion antimicrobial dialysis catheter had significantly fewer instances of surgical reintervention due to thrombosis when compared with the HemoSplit<sup>TM\*</sup> TCC with BioBloc<sup>TM\*</sup> (Palindrome<sup>TM</sup> catheter = 5, HemoSplit<sup>TM\*</sup> TCC with BioBloc<sup>TM\*</sup> = 32, n = 200, p < 0.001).

# Safety and Durability Designed for the Patient

Our dialysis catheter back-end design has been setting the standard of quality for more than 20 years.

Halkey-Roberts<sup>™\*</sup> clamps and Ultem<sup>™\*</sup> adapters are composed of durable materials.



# **Palindrome™ Precision Symmetric Tip Dialysis Catheter**

# The Clinical Challenge: Early Catheter Failure

- Poor tip position accounts for 20 percent of early catheter removals.
- Performance and durability of the catheter have been shown to improve when the catheter tip is positioned within the right atrium.<sup>11</sup>
- After insertion, early causes of low catheter blood flow rate include catheter malposition and other mechanical problems.<sup>12</sup>
- Careful attention to catheter tip position could reduce early failure rate.<sup>13</sup>



The Palindrome™ Precision dialysis catheter allows the inserting physician to :

- Easily locate the functional tip of the catheter
- Visualize the accurate placement of the tip into the right atrium using fluoroscopy and X-ray

The tungsten marker band is securely attached to the catheter using a heat-bonded process. Product testing demonstrates a robust attachment to the catheter with no detectable delamination in vitro.<sup>3</sup>



Our unique Palindrome™ Precision dialysis catheter facilitates increased tip visualization and accurate tip placement.

# **TECHNOLOGY IN PRACTICE**

# 1. Radiopaque tungsten marker

Radiopaque tungsten marker band allows the inserter to easily locate the functional tip of the catheter and visualize the placement of the tip in the right atrium on fluoroscopy and X-ray.<sup>3</sup>

# 2. Enhanced laser-cut side slots

In a computational model, the laser-cut side slots reduce total shear stress on the inflow side slot, an additional benefit to the laser-cut side slots of the Palindrome™ family of catheters.

# 3. Optimized tip geometry

Optimized tip geometry helps reduce insertion force when Tal Vena Trac™ insertion stylets are used to place a catheter.³

#### H-HEPARIN COATING

## The Clinical Challenge: Thrombosis

Catheter thrombosis can present challenges, including:

- As many as 40 percent of catheter failures are attributed to venous thrombosis and fibrin sheath formation.<sup>12</sup>
- Approximately 17–33 percent of catheter removals are attributed to thrombosis.<sup>14</sup>
- Complications from thrombosis result in inadequate flow rates, longer dialysis times, and increased costs.<sup>15</sup>



# Our Solution: Noneluting Heparin Coating Technology

Our noneluting heparin coating covers the external surface of the catheter from tip to cuff and internally from tip to adapters providing total protection.

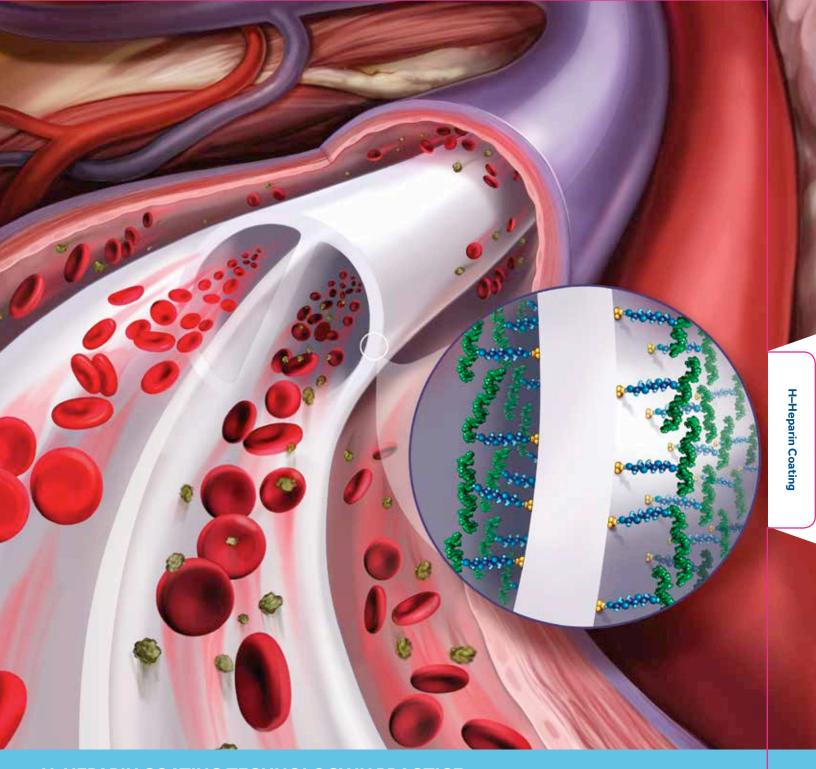
The heparin coating has a triple-action formula:

**Heparin** — **Antithrombogenic** 

Negative charge — Nonthrombogenic

Hydrophilicity — Nonthrombogenic

Our noneluting heparin coating reduces the likelihood of platelet adhesion on the catheter surface and inhibits fibrin sheath propagation.<sup>4</sup>



# H-HEPARIN COATING TECHNOLOGY IN PRACTICE

# 1. Decreases likelihood of platelet adhesion

In vivo testing demonstrated an 82 percent reduction in thrombus accumulation versus non-coated catheters. In vitro testing showed a 60 percent reduction in platelet adhesion on the surface when compared with noncoated catheters.<sup>45</sup>

# 2. Inhibits fibrin sheath propagation

noneluting heparin coating has been shown to inhibit fibrin sheath propagation when compared with noncoated catheters.<sup>4</sup>

# 3. Demonstrates long-lasting effectiveness

Tested in a shear flow model, the heparin coating remained intact after 720 hours of continuous flow, simulating 12 months of dialysis treatment.<sup>4</sup>

### SI-SILVER ION ANTIMICROBIAL SLEEVE

# The Clinical Challenge: Catheter Colonization

Catheter colonization can present challenges, including:

- The skin surrounding the catheter insertion site is one of the most common sources of microbes that colonize central venous catheters.<sup>16</sup>
- Central venous catheters colonized by skin organisms may develop biofilms and ultimately catheter-related infections.<sup>16</sup>
- The removal rate of catheters with exit-site infections is greater than 50 percent. In instances of tunnel tract infections, the rate of removal is as high as 70 percent.<sup>17</sup>

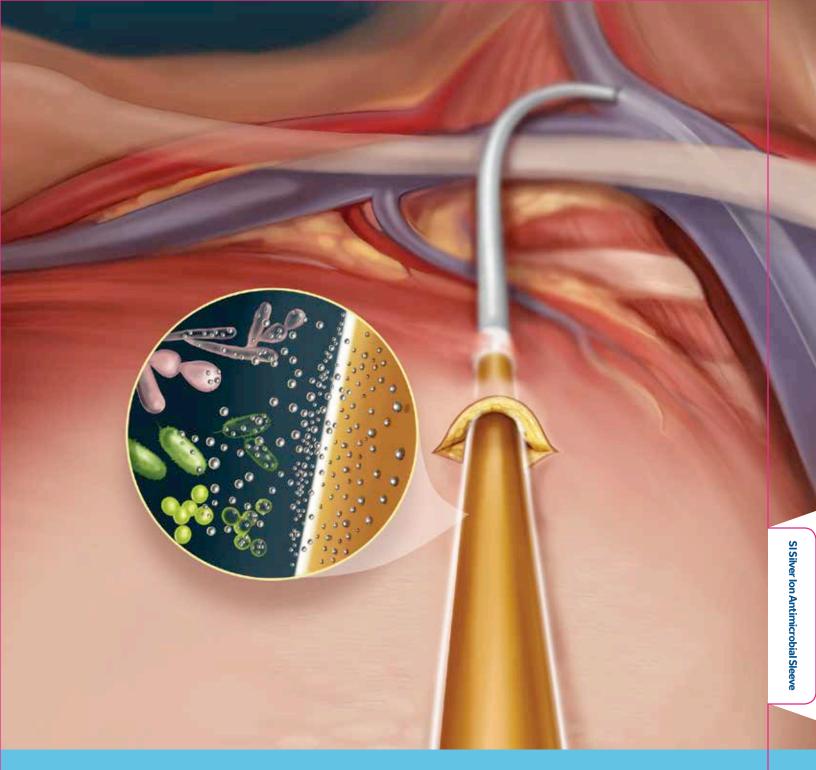


### **Silver Ion Coating Technology**

Our silver ion antimicrobial sleeve reduces colonization against a broad spectrum of bacteria on the catheter surface.

Palindrome<sup>™</sup> Precision SI dialysis catheter has been shown to have a statistically significant lower rate of reintervention for infection or thrombosis compared to a similarly coated catheter. $^{7\dagger}$ 

Our silver ion sleeve reduces colonization against a broad spectrum of bacteria on the catheter surface.<sup>5</sup>



# SILVER ION ANTIMICROBIAL SLEEVE TECHNOLOGY IN PRACTICE

# 1. Reduces colonization against a broad spectrum of bacteria on the catheter surface

In vitro testing demonstrated a significant reduction in microbial colonization compared with catheters without the sleeve. In vivo testing resulted in a significant reduction in microbial colonization compared with catheters without the sleeve. 5.18

# 2. Effective against a broad spectrum of bacteria

Protects against colonization of bacteria, yeast, and fungi, including *Staphylococcus aureus*, coagulasenegative *Staphylococcus*, *Candida albicans*, and *Escherichia coli* compared with catheters without the sleeve.<sup>5</sup>

# 3. Proven durability

The antimicrobial sleeve uses a controlled release mechanism that delivers a sustained elution of silver ions below daily tolerable intake levels.<sup>19</sup>

### HSI-COMBINED HEPARIN COATING AND SILVER ION ANTIMICROBIAL SLEEVE

# The Clinical Challenge: Thrombosis and Catheter Colonization

Catheter thrombosis and colonization can present challenges, including:

- As many as 40 percent of catheter failures are attributed to venous thrombosis and fibrin sheath formation.
- Approximately 17–33 percent of catheter removals are attributed to thrombosis.
- The skin surrounding the catheter insertion site is one of the most common sources of microbes that colonize central venous catheters.<sup>16</sup>
- Central venous catheters colonized by skin organisms develop biofilms and ultimately catheter-related infections.<sup>16</sup>

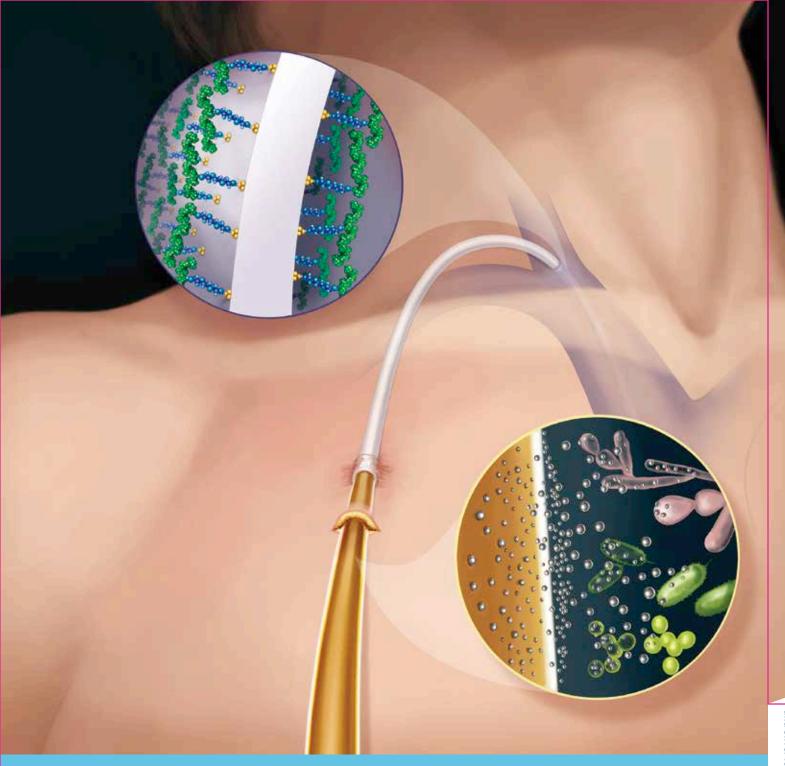


# **Combining Innovative Technologies**

Our heparin coating and silver ion antimicrobial sleeve provides

- The first chronic catheter to combine antimicrobial and antithrombogenic technologies to preserve access
- Dual protection against platelet adhesion and colonization against a broad spectrum of bacteria on the catheter surface

Reduces colonization and reduces the likelihood of platelet adhesion on the catheter surface.<sup>4,5</sup>



# HSI-COMBINED HEPARIN COATING AND SILVER ION ANTIMICROBIAL SLEEVE TECHNOLOGIES IN PRACTICE

# 1. Decreases likelihood of platelet adhesion

In vivo testing demonstrated an 82 percent reduction in thrombus accumulation, compared to noncoated catheters. In vitro testing showed a 60 percent reduction in platelet adhesion on the surface when compared with noncoated catheters. 4.5

# 2. Inhibits fibrin sheath propagation

In vivo data demonstrated that noneluting heparin coating was shown to inhibit fibrin sheath propagation compared with noncoated catheters.<sup>4</sup>

# 3. Reduces colonization

In vitro testing demonstrated that broad-spectrum colonization on the catheter surface was significantly less when compared with noncoated catheters. 5.18

### RT-REVERSE-TUNNELED DIALYSIS CATHETER

# The Clinical Challenge: Precise Catheter Placement

Precise catheter placement can present challenges, including:

- Poor tip positioning accounts for 20 percent of early catheter removals.
- After insertion, early causes of low catheter blood flow rates include catheter malposition and mechanical problems such as kinking.<sup>12</sup>
- The skin surrounding the catheter insertion site is one of the most common sources of microbes that colonize central venous catheters. <sup>16</sup>
- Successful catheter performance depends on accurate catheter tip positioning.

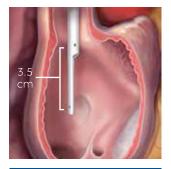
Our reverse-tunneled catheter with unique symmetric tip design and precision tip technology facilitates precise tip and cuff placement and increased tip visualization.



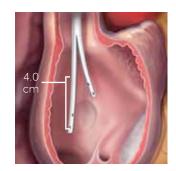
# Palindrome™ Precision RT–Reverse-Tunneled Catheter

Our unique self-flushing symmetric tip has a compact functional end compared with other competitor tip designs. This affords the inserter greater real estate in the right atrium, allowing more flexibility in positioning the catheter tip within the mid-right atrium as recommended by NKF KDOQI guidelines.<sup>20</sup>

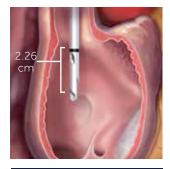




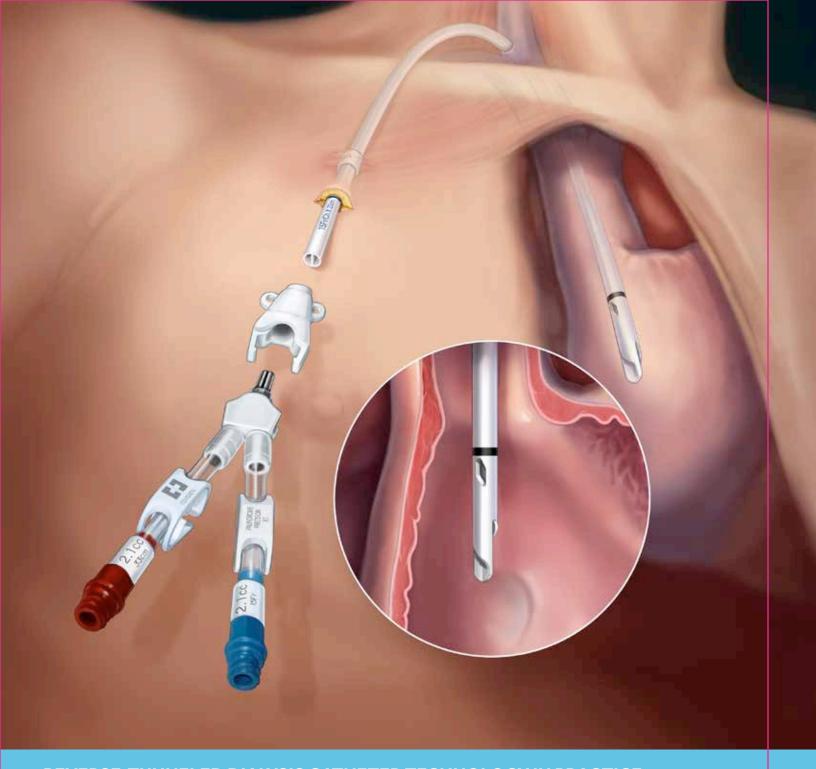
Staggered tip may limit flexibility to move vertically in right atrium



Split tip may limit flexibility to move vertically / horizontally in right atrium



Symmetric tip facilitates optimal tip placement in right atrium



# REVERSE-TUNNELED DIALYSIS CATHETER TECHNOLOGY IN PRACTICE

# 1. Precise tip placement

Compact symmetric catheter tip can be placed and positioned precisely in the right atrium. The combined RT technique and RT catheter tip design help maintain the catheter tip location in the right atrium.

### 2. Defined tunnel trajectory

Reverse-tunnel technique allows for precise placement of the catheter cuff in the tunnel tract after the tip has been placed. Proper tunnel and arc creation demonstrate model insertion techniques essential for optimal catheter placement.

# 3. "Click" hub connection assembly

Unique snap lock hub assembly facilitates attachment of the catheter to the back-end extensions, reducing the need for catheter manipulation after tip placement.

# **ORDERING INFORMATION**

# Palindrome™ Precision chronic dialysis catheter family

-				-		
				C		

Catheter	Kits	Sport Packs	Insertion Length	Overall Length
	8888145014P	8888119360P	19 cm	36 cm
	8888145015P	8888123400P	23 cm	40 cm
<b>Palindrome</b> <sup>™</sup>	8888145016P	8888128450P	28 cm	45 cm
Precision catheter	8888145017P	8888133500P	33 cm	50 cm
	8888146044P	n/a	44 cm	61 cm
	8888145018P	n/a	55 cm	72 cm
Palindrome <sup>™</sup>	8888145039P	8888119364P	19 cm	36 cm
Precision catheter with	8888145040P	8888123404P	23 cm	40 cm
Tal VenaTrac™	8888145041P	8888128454P	28 cm	45 cm
insertion stylets	8888145042P	8888133504P	33 cm	50 cm
	8888145058P	8888119370P	19 cm	36 cm
Pre-Curved Palindrome™	8888145059P	8888123410P	23 cm	40 cm
Precision catheter	8888145060P	8888128460P	28 cm	45 cm
	8888145061P	8888133510P	33 cm	50 cm
Della dasaran	8888145043P	8888119365P	19 cm	36 cm
Palindrome™ Precision	8888145044P	8888123405P	23 cm	40 cm
H-heparin coated catheter	8888145045P	8888128455P	28 cm	45 cm
cacheter	8888145046P	8888133505P	33 cm	50 cm
Pre-Curved	8888145068P	8888119371P	19 cm	36 cm
Palindrome™	8888145069P	8888123411P	23 cm	40 cm
Precision H-heparin coated catheter	8888145070P	8888128461P	28 cm	45 cm
	8888145071P	8888133511P	33 cm	50 cm
	8888145062P	8888119368P	19 cm	36 cm
<b>Palindrome</b> ™	8888145063P	8888123408P	23 cm	40 cm
Precision SI-silver ion	8888145064P	8888128458P	28 cm	45 cm
antimicrobial	8888145065P	8888133508P	33 cm	50 cm
sleeve catheter	8888146144P	n/a	44 cm	61 cm
	8888145066P	n/a	55 cm	72 cm
Palindrome™	8888145057P	8888119369P	19 cm	36 cm
Precision HSI– heparin coated	8888145048P	8888123409P	23 cm	40 cm
and silver ion	8888145049P	8888128459P	28 cm	45 cm
antimicrobial sleeve	8888145050P	8888133509P	33 cm	50 cm
	8888541019P	n/a	19 cm	39 cm
	8888541023P	n/a	23 cm	43 cm
Palindrome™ Precision	8888541028P	n/a	28 cm	48 cm
RT-reverse- tunneled catheter	8888541033P	n/a	33 cm	53 cm
camerea catricter	8888541044P	n/a	44 cm	64 cm
	8888541055P	n/a	55 cm	75 cm

#### Components

Palindrome™ Precision base, H, SI, and HSI catheters	Qty	Sport Packs	Kits
14.5Fr symmetric tip catheter	1		
VenaTrac™ over-the-wire insertion stylets	2	•	•
16Fr Valved pull-apart safety sheath	1		
Bifurcated tunneler	1		
12Fr Tissue dilator	1		
14Fr Tissue dilator	1		
Injection sealing caps	2		
18g Introducer needle	1		
J/Straight 0.038" guidewire	1		
12mL Syringe	1		
#11 Scalpel	1		
Telfa™* island dressings	2		
4" x 4" cotton gauze sponges	4		

#### Components

Palindrome™ Precision RT—reverse – tunneled catheter ■	Qty
Catheter/valve adapter assembly	1
Hub/back-end assembly with colored end cap	1
Hub snap connector	1
Tunneler	1
Additional tunneler cap	1
Syringe	1
4" x 4" Cotton gauze sponges	4
12Fr (4.0 mm) dilator	1
14Fr (4.7 mm) dilator	1
16Fr (5.3 mm) valved pull-apart safety sheath/introducer	1
Telfa™* island dressings	1
Smooth jawed forceps	2
Sealing caps	2
External measuring kit (includes 18g [1.2 mm] introducer needle, #11 scalpel, 0.038 in (0.965 mm) J/straight guidewire)	1

### **Color Key**

- Palindrome™ Precision base catheter
- Palindrome™ Precision H—heparin coated catheter
- Palindrome™ Precision SI—silver ion antimicrobial catheter
- Palindrome™ Precision HSI—heparin coated and silver ion antimicrobial catheter
- Palindrome™ Precision RT—reverse-tunneled catheter

#### **Repair Kits**

	Product Codes	Qty
Hemodialysis Catheter Repair Kit	8888200001	1
Components		
Hemodialysis Catheter Repair Kit		Qty
Arterial repair assembly		1
Venous repair assembly		1
Sealing caps		2
Temporary slide clamps		2
Drape		1
Disposable scissors		1
Measurement guide		1

Palindrome™ Precision RT– Reverse-Tunneled Catheter Kit Code ■	Length	Corresponding Palindrome™ Precision RT-Reverse-Tunneled Catheter Repair Kit
8888541019	19 cm	8888541119
8888541023	23 cm	8888541123
8888541028	28 cm	8888541128
8888541033	33 cm	8888541133
8888541044	44 cm	8888541144
8888541055	55 cm	8888541155

**Note:** Ensure that the catheter repair kit corresponds to the same implant length as the indwelling catheter so that the precalculated priming volumes located on the repair hub/back-end assembly match.

#### Components

1

Hemodialysis Catheter Repair Kit ■	Qty
Hub/back-end assembly	1
Hub snap connector	1
Smooth jawed forceps	2
Sealing caps	2
Drape	1
Ruler	1

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Priming volume label sheet

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### $\textbf{Palindrome}^{\texttt{\tiny{m}}}\,\textbf{HSI Chronic Catheter}$

The Palindrome" HSI chronic catheter with heparin coating and silver ion subcutaneous sleeve is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

The device is contraindicated in thrombosed vessels or for subclavian puncture when ventilator is in use. This product should not be used in patients with documented hypersensitivity to silver, heparin or porcine based products. Heparin coated catheters should not be used in patients with severe thrombocytopenia, uncontrollable active bleeding disorders, or with skin necrosis from previous heparin use. In case of infection, the silver in the catheter does not replace the need for using systemic anti-infective agents. Clinicians/ Healthcare Professionals should be aware that there are very limited data on prolonged and repeated use of silver containing products and particularly in children and neonates.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events.

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