

Safe  
Simple  
Support

**The SafeSept Needle Free Transseptal Guidewire system is**

**SAFE**

- ▶ The guidewire becomes atraumatic once it crosses the septum into the atrium
- ▶ Smooth, consistent motion while crossing the fossa, eliminates the "jumping effect" often associated with a transseptal needle
- ▶ Easily visualized under fluoro, echo, and mapping systems, prior to introducer advancement

**SIMPLE**

- ▶ Eliminates steps
- ▶ No RF energy needed to cross the fossa
- ▶ 85% less force to cross than a standard transseptal needle\*
- ▶ Markers designed to clearly identify guidewire location

**SUPPORT**

- ▶ Guidewire acts as a rail to support dilator advancement over the wire across the fossa
- ▶ Exchange length eliminates the need for guidewire exchange
- ▶ 2x stiffer than a super stiff guidewire\*\*

**SafeSept®**

**The SafeSept Needle Free Transseptal Guidewire system**

is a safe and simple solution for transseptal access. The unique extra stiff guidewire provides a rail and support for simple exchanges and eliminates steps. It provides an all-in-one transseptal system that doesn't require an external energy source while eliminating the "jump" often associated with transseptal crossing.

SafeSept® Needle Free Transseptal Guidewire

Needle Free® Transseptal Cannula

38° Curve 0

72° Curve 1

Not shown to scale.

# The SafeSept® Needle Free Transseptal Guidewire System

Following standard transseptal technique, the SafeSept® Needle Free Transseptal Guidewire is inserted into the hub of the Needle Free® Transseptal Cannula and advanced to the curved portion of the dilator. The transseptal dilator is advanced until it tents the fossa ovalis (figure A).

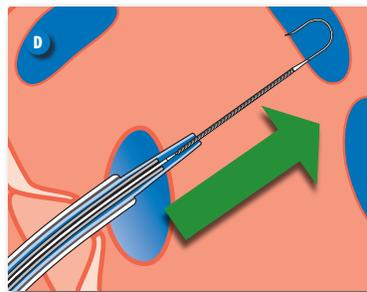
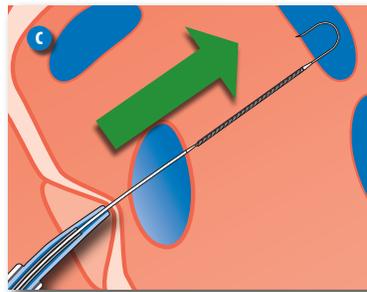
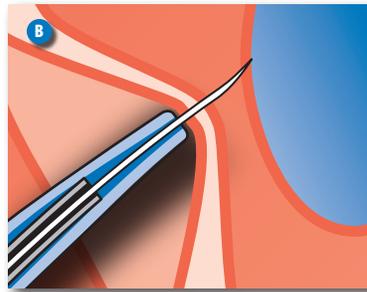
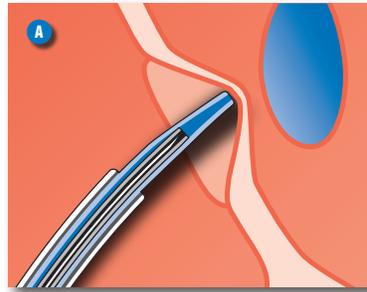
Effortless advancement of the SafeSept Needle Free tip perforates the membranous fossa (figure B).

SafeSept is slowly advanced into the left atrium (figure C). Unsupported by the introducer sheath, dilator, and Cannula the tip of the wire assumes a soft, atraumatic "J" shape, rendering it incapable of further tissue penetration.

The radiopaque coil on the shaft allows for fluoroscopic visualization of the wire within the left atrium and subsequent pulmonary vein.

Once proper guidewire location is confirmed, the NF® Transseptal Cannula, dilator and introducer sheath are advanced over the SafeSept across the septum into the left atrium with virtually no possibility of aortic or pericardial perforation (figure D).

The dilator, NF® Transseptal Cannula, and SafeSept® Needle Free Transseptal Guidewire are then removed, leaving the introducer sheath in the left atrium.



## SafeSept® Needle Free Transseptal Guidewire Features

- ▶ The soft 'J' tip of the SafeSept Needle Free Transseptal Guidewire becomes atraumatic when advanced unsupported into the left atrium.
- ▶ The SafeSept NF's tip is very small and very sharp, requiring 85% less force\* than a conventional transseptal needle, easily perforating and crossing the fossa ovalis.
- ▶ A radiopaque coil is positioned on the distal end of the SafeSept NF guidewire, providing fluoroscopic localization during the procedure.
- ▶ The included tip straightener makes it easy to insert the SafeSept NF guidewire tip into the hub of a dilator or cannula.
- ▶ Markers positioned on the proximal end of the SafeSept NF provide approximate transseptal guidewire tip locations relative to the dilator tip of most commercially available transseptal introducers.

## Needle Free® Transseptal Cannula Features

- ▶ Clear hub to visualize devices and fluids
- ▶ Light ergonomic hub with arrow indicator for curve direction
- ▶ Integrated stopcock with arrow indicator on handle
- ▶ Cannula provides column strength to any adult transseptal introducer system
- ▶ Smooth bore on inside of cannula to facilitate passage of SafeSept Needle Free Transseptal Guidewire
- ▶ Non-skiving design
- ▶ Mimics shape of standard transseptal needle curves
- ▶ Available in Curve 0 and Curve 1 shapes



## ORDERING INFORMATION

Each **SafeSept Needle Free Transseptal Guidewire** kit includes:

- ▶ One transseptal guidewire
- ▶ One tip straightener dispenser

Five (5) kits per box

Each **Needle Free Transseptal Cannula** kit includes:

- ▶ One transseptal cannula

Five (5) per box

**SafeSept Needle Free Transseptal Guidewire** Transseptal access guidewire with radiopaque coil

Model	Diameter	Length	Marker Locations**				
SSNF	0.0315 in.	180cm	67.5cm (I)	75.1cm (II)	84.4cm (III)	93.4cm (IV)	101.0cm (V)

## Needle Free® Transseptal Cannula

Model	Description	Size	Length	Curve	Curve Angle
TSC071	71cm Transseptal Cannula	18G	67.7cm	0	38°
TSC089	89cm Transseptal Cannula	18G	87.7cm	0	38°
TSC098	98cm Transseptal Cannula	18G	96.7cm	0	38°
TSC171	71cm Transseptal Cannula	18G	67.7cm	1	72°
TSC189	89cm Transseptal Cannula	18G	87.7cm	1	72°
TSC198	98cm Transseptal Cannula	18G	96.7cm	1	72°

\*Calculated from average transseptal needle and transseptal guidewire puncture forces during in vitro design qualification testing.

\*\*Calculated from 3-point bend testing of SafeSept® NF versus .032" Amplatz extra-stiff guidewire.

SafeSept is a registered trademark of Pressure Products Medical Supplies, Inc.

Patents 9,821,145; 8,992,556; 8,500,697; 8,292,910; 8,157,829; EP1542593; EP1542593; JP4496223. Other U.S. and worldwide patents pending.

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