

Device Schedule:

Intended Purpose as per the Instructions for Use:

Split Stream Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals.

Risk Classification: Class III Implantable

Basic UDI-DI: 00884908249NH

Type (Codes as per (EU) 2017/2185): MDN 1101

Model	Device Name
14F Split Stream® Catheter Sheathless Technique Sets	
S24SE.	14F x 24cm Split Stream® Double Lumen Hemodialysis Catheter Sheathless Technique Set (Cuff 19cm From Tip)
S28SE.	14F x 28cm Split Stream® Double Lumen Hemodialysis Catheter Sheathless Technique Set (Cuff 23cm From Tip)
S32SE.	14F x 32cm Split Stream® Double Lumen Hemodialysis Catheter Sheathless Technique Set (Cuff 27cm From Tip)
S36SE.	14F x 36cm Split Stream® Double Lumen Hemodialysis Catheter Sheathless Technique Set (Cuff 31cm From Tip)
S40SE.	14F x 40cm Split Stream® Double Lumen Hemodialysis Catheter Sheathless Technique Set (Cuff 35cm From Tip)
16F Split Stream® Catheter Sets	
SST2416E.	16F x 24cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)
SST2816E.	16F x 28cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)
SST3216E.	16F x 32cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)
SST3616E.	16F x 36cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)
SST4016E.	16F x 40cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)

Model	Device Name
14F Split Stream® Catheter Sets	
SST24E.	14F x 24cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)
SST28E.	14F x 28cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)
SST32E.	14F x 32cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)
SST36E.	14F x 36cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)
SST40E.	14F x 40cm Split Stream® Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)
14F Split Stream® Catheter with Stylet Sets	
SST24SE.	14F x 24cm Split Stream® Double Lumen Hemodialysis Catheter w/ Stylet Set (Cuff 19cm From Tip)
SST28SE.	14F x 28cm Split Stream® Double Lumen Hemodialysis Catheter w/ Stylet Set (Cuff 23cm From Tip)
SST32SE.	14F x 32cm Split Stream® Double Lumen Hemodialysis Catheter w/ Stylet Set (Cuff 27cm From Tip)
SST36SE.	14F x 36cm Split Stream® Double Lumen Hemodialysis Catheter w/ Stylet Set (Cuff 31cm From Tip)
SST40SE.	14F x 40cm Split Stream® Double Lumen Hemodialysis Catheter w/ Stylet Set (Cuff 35cm From Tip)