

Device Schedule:**Intended Purpose as per the Instructions for Use:**

10F Tesio®, Chronic Twinline, and Duo-Jet® II 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: 00884908278NQ

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

Model	Device Name
10F Tesio® Catheter Sets	
BFL-6E.	10F x 52cm Tesio® Dual Hemodialysis Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFL-6SE.	10F x 52cm Tesio® Dual Hemodialysis Catheter w/ Stylet Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
BFLS	10F x 52cm Tesio® Single Hemodialysis Catheter Set (Venous Cuff - 30cm From Tip)
BFR1070KDS	10F x 70cm Tesio® Dual Hemodialysis Catheter w/ Stylet Set (Arterial Cuff - 46cm From Tip) (Venous Cuff - 50cm From Tip)
BFR-6E.	10F x 52cm Tesio® Dual Hemodialysis Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFR-6SE.	10F x 52cm Tesio® Dual Hemodialysis Catheter w/ Stylet Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
BFRS	10F x 52cm Tesio® Single Hemodialysis Catheter Set (Venous Cuff - 25cm From Tip)
BFS-6E.	10F x 52cm Tesio® Dual Hemodialysis Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)

Model	Device Name
BFS-6SE.	10F x 52cm Tesio® Dual Hemodialysis Catheter w/ Stylet Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
BFSS	10F x 52cm Tesio® Single Hemodialysis Catheter Set (Venous Cuff - 21.2cm From Tip)
Chronic Twinline Catheter Sets	
NITSL21K	10F x 52cm Chronic Twinline Dual Hemodialysis Catheter Set (Arterial Cuff - 18.2cm From Tip) (Venous Cuff - 21.2cm From Tip)
NITSL25K	10F x 52cm Chronic Twinline Dual Hemodialysis Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)
Duo-Jet II Catheter Sets	
DJLT2000L	10F x 52cm Duo-Jet® II Dual Hemodialysis Catheter Set (Arterial Cuff - 27cm From Tip) (Venous Cuff - 30cm From Tip)
DJLT2000R	10F x 52cm Duo-Jet® II Dual Hemodialysis Catheter Set (Arterial Cuff - 22cm From Tip) (Venous Cuff - 25cm From Tip)