



**medCOMP**<sup>®</sup>

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## Important Field Safety Corrective Action- Product Recall

Dear Customer,

Our records indicate that you have received some of the identified products in short term hemodialysis product line. Please see the attached document for a full list of product codes and lot numbers. A product recall has been initiated for these products due to the potential for the suture wings to crack or break. **No patient injury has been reported.** Implanted catheters with intact suture wings do not need to be removed. However, an alternative method of catheter securement should be initiated for all implanted catheters, due to the potential for the suture wings to crack or break. Potential patient injury includes catheter dislocation, bleeding and air emboli.

The affected product was shipped between February 2016 and February 2018.

**Medcomp is requesting the return of all un-used affected product.** Immediately examine your inventory and quarantine product subject to recall. For any product that was further distributed, please identify the recipients and notify them at once of this product recall. Your notification may be enhanced by including a copy of this recall notification letter.

**Please note: no other product from Medcomp Brand is affected by this recall.**

Contact your customer service representative for a Returned Goods Authorization (RGA) number if necessary.

If you have any questions about this communication, please contact your distributor.

(Distributor information here)

We appreciate your assistance in this matter and apologize for any inconvenience. If you have any questions or concerns, please feel free to contact me directly.

Best regards,

Beth Giammaruti, RN MSN  
Clinical Analyst / Clinical Affairs  
Email: [complaints@medcompnet.com](mailto:complaints@medcompnet.com)  
Fax: 215-256-9191

Cc: Compliance File; Customer Service; Product Management

REF Code	Device Description	Lot Number (located on kit label)	UDI #
AAC02106	11.5F X 15CM DUO-FLOW® XTP STRAIGHT FULL SET	MCCF020 MCK440 MKAY620	884908000184
AAC02107	11.5F X 20CM DUO-FLOW® XTP STRAIGHT FULL SET	MCAW430 MCBR560	884908000191
AAC02108	11.5F X 24CM DUO-FLOW® XTP STRAIGHT FULL SET	MCCX620	884908000207
DL 11/15	11F X 15CM DOUBLE LUMEN CRRT/ABP CATHETER SET	MCAJ510 MCDQ630	541376500519
DL 11/20	11F X 20CM DOUBLE LUMEN CRRT/ABP CATHETER SET	MCAW770 MCFV450	541376500520
DL 9/15	9F X 15CM DOUBLE LUMEN CRRT/ABP CATHETER SET	MCAV080	541376500524
DL11/24	11.5F X 24CM DUO-FLOW® DOUBLE LUMEN SOFT TIP CRRT/ABP CATHETER SET	MAL840	541376500521
MCDLT114IJ	11.5F X 12CM DUO-FLOW® IJ FULL TRAY	MCAC610	884908026238
MCDLT116IJ	11.5F X 15CM DUO-FLOW® IJ FULL TRAY	MCAI590 MCCV750 MCDQ920 MCFV690	884908026276
MCDLT118IJ	11.5F X 20CM DUO-FLOW® IJ FULL TRAY	MCAH750 MCFZ550	884908026313
MCDLT3500	11.5F X 12CM DUO-FLOW® CATHETER FULL TRAY	MCFV620	884908026429
MCDLT4000	11.5F X 15CM DUO-FLOW® CATHETER FULL TRAY	MCBA170 MCDQ940 MKAX240	884908026436
MCDLT4400	11.5F X 20CM DUO-FLOW® CATHETER FULL TRAY	MCAC870 MCCQ000 MCFG380 MKAQ920	884908026443
MCDLT4424#	11.5F X 24CM DUO-FLOW® CATHETER FULL TRAY	MCAH920 MCCW950	884908026467
RMS02105	11.5F X 12CM DUO-FLOW® XTP STRAIGHT FULL SET	MKAC440	884908037616
RMS02108	11.5F X 24CM DUO-FLOW® XTP STRAIGHT FULL SET	MCC440	884908037647
T114C	11.5F X 12CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER (CATHETER ONLY)	MHMJ380 MHLV260 MJLF440	884908056419
		MHR840 MHX770 MJAZ910 MJDV230	
		MLCT530	

T114M	11.5F X 12CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCAH650 MDC910 MCFM820 MKAQ280	MCAQ240 MCDG320 MCFR060 MKAZ530	MCAW220 MCDL590 MCFV060	MCBC440 MCDW940 MKAAS20	MCCJ920 MCFAS40 MKAL360	MCCP260 MCFG000 MKAN510	884908056457
T116C	11.5F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER (CATHETER ONLY)	MCAA590 MCCG660 MKAD560	MCAD760 MCDD810 MKAL370	MCAK990 MCDG250 MKBC340	MCBM860 MCDJ980	MCBQ500 MCDP910	MCCA150 MCDV760	884908056501
T116M	11.5F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MBZS180 MCCP590 MCFI650	MCAH050 MCDD570 MCFX880	MCAI000 MCDR280 MKAB600	MCBM870 MCDX060 MKAM870	MCBT030 MCFQ250	MCCG580 MCF3300	884908056570
T116ME	11.5F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MBZY670	MCCT820	MCFQ150	MKBB070			884908056600
T116ME.	11.5F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MJLP070	MLDH060					884908056617
T118C	11.5F X 20CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER (CATHETER ONLY)	MHLM190	MHRX850	MHSY930	MHYG710	MJCV440		884908056655
T118M	11.5F X 20CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MBYR870 MCBA060 MCDX070 MKAK390	MBZM650 MCBD890 MCFA570 MKAL400	MCAH670 MCBX380 MCFD860 MKAM880	MCAJ630 MCDJ830 MCFH790 MKBA670	MCAQ250 MCDL020 MKAF320	MCAQ870 MCDR290 MKAG530	884908056709
T118ME	11.5F X 20CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCCT830						884908056747
T118ME.	11.5F X 20CM SOFT-LINE® DUO-FLOW® LUMEN CATHETER SET	MHLJ070	MHRD620	MHRX860	MJKJ070			884908056754
T119M	11.5F X 24CM SOFT LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCBC830	MCFK400					884908056808
T3500	11.5F X 12CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER TRAY	MCBH160	MCCJ940	MKAG230	MKA5240			884908056839
T4000	11.5F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER TRAY	MBZY560 MDC320 MCFQ160	MCAR110 MCDH160 MCFX190	MCBM700 MCDP900 MKAJ070	MCBZ130 MCFB210 MKAJ840	MCCK670 MCFN490 MKA5430	MCCV840 MCFP330 MIKAZ840	884908056846
T4400	11.5F X 20CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER TRAY	MBZB490 MCCK250 MKAJ420	MCAD070 MCCP870 MKAJ850	MCBB940 MCDK690 MKAP270	MCBH000 MCDP260 MKAT230	MCCN030 MCFG470	MCBT690 MCFV940	884908056853

T4424	11.5F X 24CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER TRAY	MCAK690	MCBD150	884908056860
T94C	9F X 12CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER	MCD4290		884908056891
T94M	9F X 12CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MHLQ370 MJAT510 MJGX680	MHMZ270 MJAZ020 MJKN210 MLDF860	MHTR800 MJFP340 MLDF860
T96M	9F X 15CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MHL060 MHY5090 MLBK460	MHPA230 MJGX690 MLCT650	MHSR590 MJJF710 MLBA570
T98M	9F X 20CM SOFT-LINE® DUO-FLOW® DOUBLE LUMEN CATHETER SET	MHK180 MLBG870	MHPK440	MJBJ190 MJHJ860
TRAY #414	11.5F X 15CM RAULERSON DUO-FLOW® IJ CUSTOM TRAY LANKENAU HOSPITAL	MBC900	MCGA140	884908054514
TRAY #415	11.5F X 20CM RAULERSON DUO-FLOW® IJ CUSTOM TRAY LANKENAU HOSPITAL	MCCD760		884908054521
TRAY #67	11.5F X 20CM DUO-FLOW® CATHETER FLORIDA MEDICAL CENTER CUSTOM TRAY	MCA5020 MCFJ760	MCCV750 MCDL720	884908056174
XTP1141CT	11.5F X 12CM DUO-FLOW® DOUBLE LUMEN CATHETER	MBZV810	MCFG890	884908058673
XTP1141JC	11.5F X 12CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER	MCAC560 MCDZ790	MCBD000 MCFP180	884908058703
XTP1141JC=	11F X 12CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	MCBQ850		884908058734
XTP1141JS	11.5F X 12CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MBZY880 MCCB930 MCFK060	MCAH760 MCCJ340 MCFT330	884908058765
XTP1141JS=	11F X 12CM DOUBLE LUMEN IJ CATHETER SET	MHIJ740 MHRY250 MJCH780	MHMW060 MHVX930	884908058826
XTP1141JS=JO	11F X 12CM DOUBLE LUMEN IJ CATHETER SET	MCAJ250		884908086683
XTP1141JSE	11.5F X 12CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MBZQ410 MCAT680 MCCB540 MCDT770 MKAM300	MBZV890 MCAW340 MCCB560 MCDY970 MKBA780	884908058857

XTP114MT	11.5F X 12CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MBYZ570	MCAT370	MCBF000	MCDP270	MKAH580	MKAN420	884908058895
XTP114MT=	11F X 12CM DOUBLE LUMEN CATHETER SET	MHNZ640	MHRN880	MHWY580	MJUL550	MLAX320	MLCT010	884908058925
XTP114MT-C	11.5F X 12CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCBF810						884908124286
XTP115US=	11F X 13.5CM DOUBLE LUMEN IJ CATHETER SET	MFL300						884908091960
XTP116CT	11.5F X 15CM DUO-FLOW® DOUBLE LUMEN CATHETER	MHKF210	MHLP880	MHMT220	MHNL490	MHRD110	MHSR490	884908059014
		MHXA140	MHYR000	MJBK230				
XTP116JC	11.5F X 15CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER	MBZX830	MCAX290	MCAY730	MCBF100	MCBG080	MCBQ930	884908059076
		MCBZ390	MCCQ320	MCDL600	MCDV600	MCDW870	MCFA580	
		MCFT970	MCFY800	MKAA090	MKAB620	MKAG540	MKAT120	
XTP116JC=	11F X 15CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	MHJM830	MHJV270	MHSF270	MHV8060	MHXH670	MHZR140	884908059113
XTP116JS	11.5F X 15CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MCAY880	MCBG910	MCBK800	MCBL750	MCCC150	MCCK660	884908059144
		MCDL490	MCDL620	MCDV520	MCDV990	MCFA590	MCFC020	
		MCFK070	MCFT480	MKAG550	MKAL420	MKAY970		
XTP116JS=	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	MHJT340	MHKT600	MHLD280	MHMB120	MHMT230	MHMY750	884908059267
		MHPK450	MHOA360	MHRC850	MHRY260	MHSF280	MHSN360	
		MHSP790	MHV8070	MHVN940	MHW770	MHWZ900	MHX8410	
		MHXD040	MHXG180	MHXK740	MHYH530	MHYQ620	MHYW780	
		MHZR170	MHZX910	MJAC390	MJAF850	MJAI170	MJHR000	
		MJIL560						
XTP116JS==	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	MHKT610						884908059304
XTP116JS=JO	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	MCAX940	MCAY060					884908086690
XTP116JS-1	11.5F X 15CM DUO-FLOW® IJ CATHETER SET	MBZT080	MBZX460	MCAB520	MCAJ690	MCAX720	MCBG170	884908059199
		MCBG420	MCCJ410	MCCW200	MCCX810	MCDD860	MCDY020	
		MCFG010	MCFH800	MCFK720	MCFQ290	MKAA530	MKAD270	
		MKAJ960	MKAP800	MKAS100	MKAY900	MKBA590		
XTP116JS-C	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW® IJ DOUBLE LUMEN CATHETER WITH SOFT TIP SET	MCDW200	MCDW210	MCDW240	MCDW770	MCFH680		884908106183
XTP116JSE	11.5F X 15CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MBZV100	MBZV110	MBZW110	MBZX210	MCAM280	MCAM290	884908059335
		MCAM300	MCAT690	MCAT700	MCAT710	MCAT720	MCAT730	
		MCAX340	MCAX350	MCAX810	MCAX890	MCAY900	MCAY900	

XTP116JSE.	11.5F X 15CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MCAZ670 MCBD800 MCBP860 MCCB070 MCCH000 MCCP770 MCDL760 MCDR430 MCDW650 MCF500 MCFZ020 MKAL430 MKAR600	MCBA860 MCBF220 MCBP870 MCCC850 MCCH270 MCCQ400 MCDL030 MCDR730 MCFA620 MCF510 MCFZ030 MKAL440 MKAR610	MCBB220 MCBF770 MCBY130 MCCD220 MCCH280 MCCX080 MCDL080 MCDT220 MCFP380 MCFX890 MCFZ040 MKAL540 MKAT730	MCBC110 MCBG100 MCBY140 MCCD390 MCCI090 MCCX090 MCDL290 MCDT230 MCFP390 MCFX900 MCFZ050 MKAL550 MKAW690	MCBC640 MCBM790 MCCA470 MCCF350 MCCN170 MCDA550 MCDL330 MCDV880 MCFR490 MCFZ000 MKAG560 MKAN430 MKAX670	MCBC960 MCBN110 MCCB060 MCCF760 MCCN180 MCDL750 MCDR390 MCDW630 MCFR490 MCFZ010 MKAH630 MKAN440	884908059342
XTP116JIS-ID	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW IJ DOUBLE LUMEN CATHETER W/SOFT TIP SET, W/MINI SCALPEL, SYRINGE AND NEEDLE	MCA620	MCAT780	MKAK760				884908059175
XTP116JIS-J	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW® IJ DOUBLE LUMEN CATHETER WITH SOFT TIP SET	MCBW280	MCC690	MCCM070	MCCY530	MCDP280		884908059182
XTP116MT	11.5F X 15CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MHKF220 MHXL200	MHND730 MHYS160	MHQZ520 MJLP100	MHSR600	MHVC650	MHVZ510	884908059380
XTP116MT=	11F X 15CM DOUBLE LUMEN CATHETER SET	MHJW760 MHR1890 MHZ090	MHKL220 MHRX890 MJAC400	MHMZ290 MHSD980 MJAL920	MHNS580 MHTH960 MJBG320	MHPF900 MHTQ210 MJBP200	MHQK920 MHXY000 MJDC370	884908059434
XTP116MT==	11F X 15CM DOUBLE LUMEN CATHETER SET	MHSF620	MJGT620	MLBA580				884908059465
XTP116MT===	11F X 15CM DOUBLE LUMEN CATHETER SET	MHJ980 MHXL210 MJFB330	MHQ200 MHZF060 MJHR380	MHK1230 MHZ1100 MJL570	MHRJ900 MIAK690 MJJP430	MHRX900 MJB080 MJY710	MHSM570 MJBX730 MLBW960	884908059472
XTP116MTE	11.5F X 15CM DUO-FLOW DOUBLE LUMEN CATHETER SET	MHKF330	MHRB840	MHVX400	MHXL220	MHYR010		884908059496
XTP116T-J	11.5F X 15CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCAV620 MCFP970	MCBL170 MCFV270	MCBY440 MKAG020	MCDN160 MKAR230	MCDT980	MCF960	884908059540
XTP118CT		MCA8010	MCAH390	MCCB410	MCCP800	MCBZ910	MCC1040	884908059564



XTP118MT===	11F X 20CM DOUBLE LUMEN CATHETER SET	MLBA600	MHYG860 MIJL580	MHZ290 MIJL550	MJAQ560 MIJMD580	MJAY110	MJBF030	884908059922
XTP118MT-C	11.5F X 20CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	M CBD590	M CBG760					884908126488
XTP118MTE	11.5F X 20CM DUO-FLOW DOUBLE LUMEN CATHETER SET	MHJT360 MHVX280 MJHR400	MHNZ430 MHXL910 MIJQ710	MHOA380 MHYA320 MIJCM370	MHRB850 MHZT970 MLBG470	MHSM610 MJFA360	MHSY580 MJGC640	884908059946
XTP118MT-ID	11.5F X 20CM DUO-FLOW DOUBLE LUMEN CATHETER W/SOFT TIP SET, W/MINI SCALPEL, SYRINGE, AND NEEDLE	MCDW910						884908059854
XTP118T-J	11.5F X 20CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCAG410	MCAT790	MCBL290	MCBS610	MCCF240	MCFC100	884908059991
XTP119CT	11.5F X 24CM DUO-FLOW® DOUBLE LUMEN CATHETER	MCCG670	MCCQ550					884908060027
XTP119MT	11.5F X 24CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MHKF230	MHQZ530	MJDS460	MJLP110			884908060041
XTP119MT=	11F X 24CM DOUBLE LUMEN CATHETER SET	MHJS170 MHRF780 MHZT980 MLDF870	MHKS240 MHVB690 MIJLP120 MLDH930	MHMZ300 MHVS860 MIJMD590	MHNS810 MHXD650 MLAK410	MHPC980 MHXG200 MLAK420	MHOA940 MHZF590 MLBA610	884908060065
XTP119MTE	11.5F X 24CM DUO-FLOW DOUBLE LUMEN CATHETER SET	MHJF530	MHKT960	MHLF260	MHPC950	MHTV740	MJAA970	884908060072
XTP119T-J	11.5F X 24CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	M CB1000	MCCB880	MCFL380	MCFP980	MKAG030	MKA5360	884908060102
XTP94CT	9F X 12CM DUO-FLOW® DOUBLE LUMEN CATHETER	M CBA920	MCDG510	MCDH590				884908061079
XTP94IJS	9F X 12CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	M BZB460 MCDT540	M BZ990 MCDT880	M CBC840 MCF5940	MCCD240	MCCP250	MCDL670	884908061116
XTP94IJS=	9F X 12CM IJ CATH SET	M CAB890	MCCJ970	MCFT850	MKAF460			884908061147
XTP94MT	9F X 12CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCAV020 M CDA800 M CFT170	MCAZ480 MCDJ300 MKAD730	M CBD160 MCDJ300 MKAH230	M CBG700 M CFF150 MKAL500	MCCN590 M CFF780 MKAQ470	MCCQ560 M CFF060	884908061161
XTP94MT=	9F X 12CM DOUBLE LUMEN CATHETER SET	M BZS030 M CBZ350 MCDM770 M KBA420	M CAM160 M CCC690 MCDN620	M CAY210 MCCP270 MCDW970	M CBF020 M CCS690 MKAJ140	M CBG540 MCCZ050 MKAL900	M CBN560 M CDA350 M KAN710	884908061185
XTP94MTE.	9F X 12CM(4-3/4") DUO-FLOW® DOUBLE LUMEN CATHETER SET	M CBA200	M CDA260	M CDA310	M CFF180			884908061192



XTP96IJS	9F X 15CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MCAF080	MCAM120	MCBD990	MCBP300	MCCD040	MCCQ950	884908061253
XTP96IJS=	9F X 15CM INTERNAL JUGULAR CATHETER SET	MCDB810	MCDJ710	MCFT340				884908061284
XTP96IJS-J	9F X 15CM IJ DOUBLE LUMEN CATHETER SET	MCDS480	MKAP710	MKBG590				884908061277
XTP96MT	9F X 15CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCA570	MCAM130	MCAP330	MCBC460	MCBG520	MCBY460	884908061314
XTP96MT=	9F X 15CM DOUBLE LUMEN CATHETER SET	MCCN840	MCCY370	MCDA700	MCDN010	MCDW960	MCDY490	
XTP96T-J	9F X 15CM DOUBLE LUMEN CATHETER SET	MCDY900	MCF580	MCFR440	MCFV680	MKAD740	MKAF790	
XTP98CT	9F X 20CM DUO-FLOW® DOUBLE LUMEN CATHETER	MKAG870	MKAP280					
XTP98IJS	9F X 20CM RAULERSON DUO-FLOW® IJ DOUBLE LUMEN CATHETER SET	MHNZ630	MHQC250	MHSN210	MJCV830	MJLQ630	MLCL520	884908061345
XTP98MT	9F X 20CM DUO-FLOW® DOUBLE LUMEN CATHETER SET	MCAZ490	MHQC250	MHSN210	MJCV830	MJLQ630	MLCL520	884908061369
XTP98T-J	9F X 20CM DOUBLE LUMEN CATHETER SET	MCDN710						884908061376
		MCCF730	MCCN530	MCDD430	MCDV950	MCFT260		884908061406
		MBZQ280	MCAL970	MCBF520	MCCM220	MCDR490	MKAN470	884908061444
		MBWY270	MCBX160	MCCM080	MCFL390			884908061482