



**medCOMP**

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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 MCFK440 MKAY620	884908000184
AAC02107	11.5F X 20CM DUO-FLOW* XTP STRAIGHT FULL SET	MCCR560	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 MCCJ250 MCDJ160	541376500519
DL 11/20	11F X 20CM DOUBLE LUMEN CRRT/ABP CATHETER SET	MCDQ630 MCFE200 MCFV440 MKAK310	541376500520
DL 9/15	9F X 15CM DOUBLE LUMEN CRRT/ABP CATHETER SET	MCAW770 MCCJ690 MCFB450	541376500524
DL11/24	11.5F X 24CM DUO-FLOW* DOUBLE LUMEN SOFT TIP CRRT/ABP CATHETER SET	MCAV210 MCBW440 MCCA030 MCHH330	541376500521
MCDLT114IJ	11.5F X 12CM DUO-FLOW* II FULL TRAY	MCCB800 MCBW450 MCHH690	884908026238
MCDLT116IJ	11.5F X 15CM DUO-FLOW* II FULL TRAY	MCA610 MCB560	884908026276
MCDLT118IJ	11.5F X 20CM DUO-FLOW* II FULL TRAY	MCA580 MCBH130 MCBN350 MCBY390	884908026313
MCDLT3500	11.5F X 12CM DUO-FLOW* CATHETER FULL TRAY	MCCV240 MCDG860 MCDJ730 MCDP710	884908026429
MCDLT4000	11.5F X 15CM DUO-FLOW* CATHETER FULL TRAY	MCFB850 MCFD630 MCFM700 MCF5710	884908026436
MCDLT4400	11.5F X 20CM DUO-FLOW* CATHETER FULL TRAY	MCFV690 MKAD790 MKAT090 MKAX630	884908026443
MCDLT4424#	11.5F X 24CM DUO-FLOW* CATHETER FULL TRAY	MCAH750 MCBY520 MCFD640 MCFQ350	884908026467
RMS02105	11.5F X 12CM DUO-FLOW* XTP STRAIGHT FULL SET	MKAR100 MKAZ210	884908037616
RMS02108	11.5F X 24CM DUO-FLOW* XTP STRAIGHT FULL SET	MCKB870 MCB5910 MCBZ450 MCCP990	884908037647
TL114C	11.5F X 12CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER (CATHETER ONLY)	MCDN100 MCFD710 MCFN970 MCF5730	884908056419
		MCA5340 MCBAR80 MCBY910 MCCF130	
		MCCX150 MCDJ010 MCDG980 MCDP120 MCFD720	
		MCFJ060 MCFM520 MCFW900 MCFZ590 MKAJ380	
		MCA5230 MCBL150 MCBN500 MCCV010	
		MCDJ030 MCFX080	
		MKAC440	
		MCHH440	
		MHJV260 MHRF770 MJAZ910 MJOV230	
		MJLF440 MML380 MHRF770 MJAZ910 MJOV230	
		MMLT530	

T114M	11.5F X 12CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER SET	MCAH650 MDCG910 MCFM820 MKAQ280	MCAQ240 MCDG320 MCFR060 MKA2530	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)	MCAAS90 MCCG660 MKAD360	MCAD760 MCD0810 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 MCF1650	MCAH050 MCD0570 MCFX880	MCAL000 MCDR280 MKAB600	MCBM870 MCDX060 MKAM870	MCBT030 MCFQ250	MCCG580 MCF5300	884908056570
T116ME	11.5F X 15CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER SET	MBZV670	MCCT820	MCFQ150	MKBB070			884908056600
T116ME	11.5F X 15CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER SET	MILP070	MILDH060					884908056617
T118C	11.5F X 20CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER (CATHETER ONLY)	MHLM190	MHRX850	MHSY930	MHYG710	MJCX440		884908056655
T118M	11.5F X 20CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER SET	MBYR870 MCBA060 MCDX070 MKAK390	MBZM650 MCBD890 MCFAS70 MKAL400	MCAH670 MCBX380 MCFD860 MKAM880	MCAJ630 MCDR830 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	MJKI070			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	MKAS240			884908056839
T4000	11.5F X 15CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER TRAY	MBZV560 MCD0320 MCFQ160	MCAR110 MCDH160 MCFX190	MCBM700 MCDP900 MKAF070	MCBZ130 MCFB210 MKAJ840	MCCK670 MCFM490 MKA5430	MCCV840 MCFP330 MKAZ840	884908056846
T4400	11.5F X 20CM SOFT-LINE* DUO- FLOW* DOUBLE LUMEN CATHETER TRAY	MBZB490 MCCX250 MKA420	MCAD070 MCCP870 MKA850	MCB8940 MCDR690 MKAP270	MCBH000 MCDP260 MKAT230	MCBM030 MCFG470	MCBT690 MCFV940	884908056853

T4424	11.5F X 24CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER TRAY	MCAK690	M CBD150	884908058860		
T94C	9F X 12CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER	M CDA290		884908058891		
T94M	9F X 12CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER SET	MHLQ370 MJA7510 MJGX680 MJRN210	MHMS190 MJA2020 MJP090 MLDF860	MHTR800 MJFP340 MUGC620	884908058907	
T96M	9F X 15CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER SET	MHL060 MHY5090 MLBK460	MHPA230 MJGX690 MLCT650	MHSR590 MJJF710	884908058945	
T98M	9F X 20CM SOFT-LINE* DUO-FLOW* DOUBLE LUMEN CATHETER SET	MHKJ180 MLBG870	MHPK440	MHRN870 MJBP190	MJHJ860	884908058983
TRAY #414	11.5F X 15CM RAULERSON DUO-FLOW* U CUSTOM TRAY LANKENAU HOSPITAL	MCBC900	M CCGA140	884908054514		
TRAY #415	11.5F X 20CM RAULERSON DUO-FLOW* U CUSTOM TRAY LANKENAU HOSPITAL	MCCD760		884908054521		
TRAY #67	11.5F X 20CM DUO-FLOW* CATHETER FLORIDA MEDICAL CENTER CUSTOM TRAY	MCA5020 MCFJ760	MCCV750 MKA6880	MCCD1720 MCDV440	884908056174	
XTP114CT	11.5F X 12CM DUO-FLOW* DOUBLE LUMEN CATHETER	MBZV810	MCF6890	884908058673		
XTP114UC	11.5F X 12CM RAULERSON DUO-FLOW* U DOUBLE LUMEN CATHETER	MCAC560 MCDZ790	M CBW980	MCCP130 MCDV260	884908058703	
XTP114UC=	11F X 12CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	MCBQ850		884908058734		
XTP114US	11.5F X 12CM RAULERSON DUO-FLOW* U DOUBLE LUMEN CATHETER SET	MBZV880 MCCB930 MCFK060	MCA1150 MCCN900 MKAB610	MCBF510 MCDV830 MKAN410	884908058765	
XTP114US=	11F X 12CM DOUBLE LUMEN U CATHETER SET	MHUV740 MHRV250 MJCH780	MHMW060 MHXA200	MHNS800 MHXK730	884908058826	
XTP114US=10	11F X 12CM DOUBLE LUMEN U CATHETER SET	MCAJ250		884908086683		
XTP114NSE	11.5F X 12CM RAULERSON DUO-FLOW* U DOUBLE LUMEN CATHETER SET	MBZQ410 MCAT680 MCBP540 MCCD770 MKAM300	MBZV890 MCAW340 MCCZ880 MCDY970 MKBA780	MCAT660 MCBG440 MCCJ110 MKAD710	884908058857	

XTP114MT	11.5F X 12CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MBV2570	MCAT370	MCBF600	MCDP270	MKAH580	MKAN420	884908058895
XTP114MT=	11F X 12CM DOUBLE LUMEN CATHETER SET	MHNZ640	MHRN880	MHWY580	MJL550	MLA320	MLCT010	884908058525
XTP114MT-C	11.5F X 12CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MCFB810						884908124286
XTP115JUS=	11F X 13.5CM DOUBLE LUMEN II CATHETER SET	MFL300						884908091960
XTP116CT	11.5F X 15CM DUO-FLOW* DOUBLE LUMEN CATHETER	MHKF210	MHP880	MHMT220	MHNL490	MHRD110	MHSR490	884908059014
		MHXA140	MHYR000	MJBK230				
XTP116JIC	11.5F X 15CM RAULERSON DUO-FLOW* II DOUBLE LUMEN CATHETER	MBZX830	MCAX290	MCAV730	MCBF100	MCBG080	MCBQ930	884908059076
		MCBZ390	MCCQ320	MDCB560	MCDL600	MCDW870	MCFAS80	
		MCFY970	MCFY800	MKAA090	MKAB620	MKAG540	MKAT120	
XTP116JIC=	11F X 15CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	MHJM830	MHPV270	MHSF270	MHV8060	MHXH670	MHZR140	884908059113
XTP116JIS	11.5F X 15CM RAULERSON DUO-FLOW* II DOUBLE LUMEN CATHETER SET	MCAV880	MCBG910	MCBK800	MCBL750	MCCC150	MCCK660	884908059144
		MCDCA90	MCDL620	MCDV520	MCDV990	MCFAS90	MCFCD20	
		MCFK070	MCFY480	MKAG550	MKAL420	MKAY970		
XTP116JIS=	11F X 15CM DOUBLE LUMEN II CATHETER SET	MHJT340	MHKT600	MHLD280	MHMB120	MHMT230	MHMV750	884908059267
		MHPK450	MHQQA360	MHRC850	MHRY260	MHSF280	MHSN360	
		MHSP790	MHV8070	MHVN940	MHW0770	MHW2900	MHXB410	
		MHXD040	MHXG180	MHXK740	MHYH530	MHYQ620	MHYV780	
		MHZR170	MHZX910	MJAC390	MJAF850	MJAJ170	MJHR000	
		MJL560						
XTP116JIS==	11F X 15CM DOUBLE LUMEN II CATHETER SET	MHKT610						884908059304
XTP116JIS=J0	11F X 15CM DOUBLE LUMEN II CATHETER SET	MCAV940	MCAY060					884908086590
XTP116JIS-1	11.5F X 15CM DUO-FLOW* II CATHETER SET	MBZT080	MBZX460	MCAB520	MCAJ690	MCAX720	MCBG170	884908059199
		MCBG420	MCCJ410	MCCW200	MCCX810	MCD0860	MCDY020	
		MCFG010	MCFH800	MCFK720	MCFQ290	MKAA530	MKAD270	
		MKAJ960	MKAP800	MKAS100	MKAY900	MKBA590		
XTP116JIS-C	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW* II DOUBLE LUMEN CATHETER WITH SOFT TIP SET	MCDW200	MCDW210	MCDW240	MCDW770	MCFH680		884908106183
XTP116JIS-E	11.5F X 15CM RAULERSON DUO-FLOW* II DOUBLE LUMEN CATHETER SET	MBZV100	MBZV110	MBZV130	MBZV210	MCAM280	MCAM290	884908059335
		MCAM300	MCAT690	MCAT700	MCAT710	MCAT720	MCAT730	
		MCAV340	MCAX350	MCAX810	MCAY890	MCAY900	MCAZ660	

XTP116USE	11.5F X 15CM RAULERSON DUO-FLOW* II DOUBLE LUMEN CATHETER SET	MCA2670 MCB8460 MCBB220 MCBF770 MCBP870 MCCB850 MCCB070 MCCH000 MCCP770 MCCD760 MCDR430 MCDW650 MCF7500 MCFZ020 MKAL430 MKAR600	MCB220 MCBF770 MCBY130 MCCD220 MCCD280 MCCQ400 MCDL030 MCDL080 MCDT220 MCFP380 MCFX890 MCFZ040 MKAL540 MKAT730	MCBC110 MCBG100 MCBY140 MCCD390 MCCD090 MCCX090 MCDL290 MCDT230 MCFP390 MCFX900 MCFZ050 MKAL550 MKAW690	MCBC540 MCBM790 MCCA470 MCCF350 MCCN170 MCDA550 MCDL330 MCDV880 MCFR490 MCFZ000 MKAG560 MKAN430 MKAX670	MCBC960 MCBN110 MCCB060 MCCF760 MCCN180 MCDL750 MCDR390 MCDW530 MCF7490 MCFZ010 MKAH630 MKAN440	884908059342
XTP116US-ID	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW II DOUBLE LUMEN CATHETER W/SOFT TIP SET, W/MINI SCALPEL, SYRINGE AND NEEDLE	MCA2620	MCAK760				884908059175
XTP116US-J	11.5F X 15CM RAULERSON PRE-CURVED DUO-FLOW* II DOUBLE LUMEN CATHETER WITH SOFT TIP SET	MCBW280	MCCM070	MCCY530	MCDP280		884908059182
XTP116MT	11.5F X 15CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MHKF220 MHXL200 MHJW760 MHRJ890 MHZX090 MJFP350 MHSF620	MHQZ520 MJLP100 MHMZ290 MHS0980 MJAL920 MLBA580	MHSR600 MHNS580 MHTH960 MJBG320	MHVC650 MHFP900 MHTQ210 MJBP200	MHVZ510 MHQR920 MHRX000 MUDC370	884908059380
XTP116MT=	11F X 15CM DOUBLE LUMEN CATHETER SET	MHJ980 MHXL210 MJFB330	MHKL230 MHZX100 MJJL570	MHR1900 MIAK690 MJJP430	MHRX900 MJB0080 MJJY710	MHSM570 MJBX730 MLBW960	884908059434
XTP116MT==	11F X 15CM DOUBLE LUMEN CATHETER SET	MHRB840	MHVX400	MHXL220	MHYR010		884908059465
XTP116MT===	11F X 15CM DOUBLE LUMEN CATHETER SET	MCAV620 MCFP970	MCBY440 MKAG020	MCDN160 MKAR230	MCDT980	MCFP960	884908059472
XTP116MTE	11.5F X 15CM DUO-FLOW DOUBLE LUMEN CATHETER SET	MCA8010	MCCB610	MICBP800	MICB2910	MCC040	884908059496
XTP116T-J	11.5F X 15CM DUO-FLOW* DOUBLE LUMEN CATHETER SET						884908059540
XTP118CT							884908059564



XTP118MT===	11F X 20CM DOUBLE LUMEN CATHETER SET	MLRA600	MHYG860 MUJ580	MHYZ290 MILG550	MJAC560 MUJMD580	MJAY110	MIBF030	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	MHQZ430 MHXL910 MUJQ710	MHOA380 MHYA320 MJKM370	MHR8850 MHZ7970 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	M CBL290	M CBS610	M CCF240	M CFC100	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	MIDS460	MULP110			884908060041
XTP119MT=	11F X 24CM DOUBLE LUMEN CATHETER SET	MHJS170 MHRF780 MHZT980 MLDF870	MHKS240 MHV8690 MULP120 MLDH930	MHMZ300 MHVS860 MUMD590	MHNSB10 MHXD650 MLAK410	MHPC980 MHKG200 MLAK420	MHOA940 MHZF590 MLBA610	884908060065
XTP119MTE	11.5F X 24CM DUO-FLOW DOUBLE LUMEN CATHETER SET	MHJF530	MHKT960	MHJF260	MHPC950	MHTV740	MJAA970	884908060072
XTP119T-J	11.5F X 24CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	M CB1000	MCCB880	M CFL380	M CFP980	M KAGO30	M KAS360	884908060102
XTP94CT	9F X 12CM DUO-FLOW* DOUBLE LUMEN CATHETER	M CBA920	M CDG510	M CDH590				884908061079
XTP94IJS	9F X 12CM RAULERSON DUO-FLOW* II DOUBLE LUMEN CATHETER SET	M BZB460 M CD1540	M BZ2990 M CD1880	M CBC840 M CFS940	M CCD240	M CCP250	M CDL670	884908061116
XTP94IJS~	9F X 12CM II CATH SET	M CAB890	M CCJ970	M CFT850	M KA460			884908061147
XTP94MT	9F X 12CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MCAV020 M CDA800 M CFT170	MCAZ480 M CDC240 M KAD730	M CBD160 M CDJ300 M KAH230	M CBG700 M CFF150 M KAL500	M CCN590 M CFF780 M KAQ470	M CCQ560 M CFH060	884908061161
XTP94MT~	9F X 12CM DOUBLE LUMEN CATHETER SET	M BZ5030 M CBZ350 M CDM770 M KBA420	M CAM160 M CCC690 M CDM620	M CAY210 M CCP270 M CDW970	M CBF020 M CCS690 M KA1140	M CBG540 M CCZ050 M KAL900	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* U DOUBLE LUMEN CATHETER SET	MCAF080 MCD8810	MCAM120 MCDJ710	MCBD990 MCF340	MBCP300	MCCD040	MCCQ950	884908061253
XTP96IJS=	9F X 15CM INTERNAL JUGULAR CATHETER SET	MCD5480	MKAP710	MKBG590				884908061284
XTP96IJS-J	9F X 15CM U DOUBLE LUMEN CATHETER SET	MKAJ710						884908061277
XTP96MT	9F X 15CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MCAC570 MCCN840 MCDY900 MKAGB70	MCAM130 MCCY370 MCF580 MKAP280	MCAP330 MCDA700 MCFR440	MCBC460 MCDN010 MCFV680	MCBG520 MCDW960 MKAD740	MCBY460 MCDY490 MKAF790	884908061314
XTP96MT=	9F X 15CM DOUBLE LUMEN CATHETER SET	MHNZ630	MHQC250	MHSN210	MJCV830	MJLD630	MJLD520	884908061345
XTP96T-J	9F X 15CM DOUBLE LUMEN CATHETER SET	MCAZ490	MHQC250	MHSN210	MJCV830	MJLD630	MJLD520	884908061369
XTP98CT	9F X 20CM DUO-FLOW* DOUBLE LUMEN CATHETER	MCDN710						884908061376
XTP98IJS	9F X 20CM RAULERSON DUO-FLOW* U DOUBLE LUMEN CATHETER SET	MCCF730	MCCN530	MCCD430	MCDV950	MCFT260		884908061406
XTP98MT	9F X 20CM DUO-FLOW* DOUBLE LUMEN CATHETER SET	MBZQ280	MCAI970	MCBF520	MCCM220	MCDR490	MKAN470	884908061444
XTP98T-J	9F X 20CM DOUBLE LUMEN CATHETER SET	MBWY270	MCBX160	MCCM080	MCFI390			884908061482