

URGENT PRODUCT RECALL NOTIFICATION

September 1, 2009

ATTN: Risk Manager/ Materials Manager

REFER TO ATTACHMENT FOR A COMPLETE LIST OF AFFECTED PRODUCTS AND LOT NUMBERS FOR YOUR FACILITY

To Whom It May Concern:

Medical Device Technologies, Inc., dba Angiotech, has initiated a voluntary recall for products referenced on the attached page. There have been no reports of patient injury. Our customer records indicate that your facility received product shipped between March 1, 2009 and August 11, 2009 that may contain product with a run-off seal. We have determined the root cause of this failure and have implemented the necessary corrective actions. In addition, any product received with a green sticker has been previously inspected and was found not to be impacted by the recall.

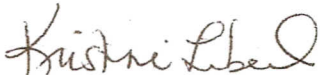
Please review your current inventory and segregate the affected lot numbers. To ensure our customers have received this notification and to arrange for credit and the return of identified product, please complete the attached Customer Acknowledgment Form and return via fax to our Quality Assurance department at 1.352.338.0662 or 1.800.333.0440.

The returned Customer Acknowledgment form ensures our customers have received this notification and to arrange for credit and the return of identified product.

Please note, if you are a distributor of this product, you are responsible for notifying any customer you may have sold the product to. This recall is to the retail level.

We apologize for any inconvenience this may have caused you or your staff. If you have any questions concerning this notification, please contact Shannon Brooks at (352) 338.0440 ext. 355 or Katrenia Williams at ext. 353.

Regards,



Kristine Liberacki
Sr. Compliance Manager
Medical Device Technologies, Inc., dba Angiotech

MEDICAL DEVICE TECHNOLOGIES, Inc. dba ANGIOTECH—CUSTOMER ACKNOWLEDGMENT FORM
PRODUCT RECALL
SEPTEMBER 1, 2009

Customer Name: _____

Customer Account Number: _____

Address: Street: _____

City: _____

State: _____ Zip: _____

Customer Contact Name: _____

Contact Phone Number: _____

Signature of the Individual Completing the Acknowledgement Form

Date

Please examine your inventory on hand, select the statement that applies to your facility:

☐ We have no affected inventory in stock

☐ We have affected inventory in stock and the following products will need to be returned.

Product Number	Lot Number	Qty	Unit of Measure		
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	
			☐ Each	☐ Box	

(To be completed by Angiotech Quality personnel) RMA # _____ Date Assigned: _____

Assigned By: _____

Forms may be **faxed** to the attention of the Quality Assurance Department at **352.338.0662 or 1.800.338.0662**

«Ship_Name»
«Ship_City» «State»

EU PRODUCT LIST

Product	Part Number	Lot Numbers	510(k)	Class	Description	MDD Class	GMDN Code	GMDN Term
Accura BLN	BLN2003, BLN2005, BLN20075, BLN2103, BLN2105, BLN21075	90621SZN, 91051TTN, 91591UV4, 90571SVW, 90571SVX, 90681T3E, 90911TK7, 91181TW9, 91271U9Y, 91561UU6, 90571SUJ, 90571SUK, 90681T46, 90831TA6, 90921TKY, 90961TLT, 91051TTS, 91131TZD, 91131U08, 91201U5P, 91471UNO, 91541US2, 91631UZT, 90891TGR, 90701T5A, 90961TM1, 91031TM2, 91341UF3, 91481UO9, 90751T6X, 90751T6Y, 91051TTL, 91131TZ7, 91541US1, 91551UT0	K974741	I	Breast Localization Needle	Ila	40808	Marker, lesion localization, implantable
ACCURA II BLN	266050, 266075	90491SOM, 90821T2V, 91061TTU, 91121TXX, 91041TOI				Ila	40808	Marker, lesion localization, implantable
HAWKINS I BLN	251050, 251075, 251100	90551STU, 91461ULZ, 91491UPP, 90551STT, 90681T42, 90921TKW, 90901TIZ, 91561UTY				Ila	40808	Marker, lesion localization, implantable
HAWKINS II BLN	242050, 242075, 252050, 252075	90541SRB, 91171TW7, 91311UBE, 90681T3N, 91311UBF, 91481UOA, 90541SS4, 90701T5G, 90971TOJ, 91171U2A, 91461UMQ, 90611SY7, 90891TH1, 91131TZT, 91471UNJ				Ila	40808	Marker, lesion localization, implantable
HAWKINS III BLN	243030, 243050, 243075, 244030, 244050, 244075, 253030, 253050, 253075	91331UCJ, 90571SW1, 90641T1V, 91181U2T, 90551SUD, 90611SXX, 90901TJ3, 91271U9X, 91461UML, 90571SUV, 90821TCM, 90961TM3, 91411UKL, 90551SUE, 90641T1W, 90821TCN, 91061TUI, 91341UFK, 91461UMK, 91681V2T, 90611SXV, 90701T5M, 91131TZK, 91271U9V, 90641T22, 90681T39, 90681T3A, 90771T9T, 90821TCW, 90901TIK, 90971TNO, 91051TTT, 91271UA4, 91331UCR, 90551SU9, 90551SUA, 90571SVT, 90771TAE, 90891THJ, 91061TUP, 91331UCQ, 91471UNM, 91551UT2, 91741V6K	K870523	I		Ila	40808	Marker, lesion localization, implantable
HOMER MAMMALOK GOLD	231030G, 231050G, 231075G, 231100G, 231125G	90411SIV, 90541SSU, 90641T1Y, 91131TZS, 90541SRF, 90631TOZ, 90751T7Q, 90841TEE, 91031TRX, 91271UA0, 91341UFS, 91391UHY, 90541SSD, 90781TBI, 90901TJA, 91271TUQ, 91491UPH, 91551UT3, 90901TJ8, 91561UU7, 90981TPU, 91131TZU	Exempt	I		Ila	40808	Marker, lesion localization, implantable
D WIRE BLN	BLND20075	90611SYG, 91131TZB	K974741	I		Ila	40808	Marker, lesion localization, implantable
PRO-MAG "SHORT THROW" BIOPSY NDL	765114080, 765116120, 765114120, 765118080, 765118120	90831TDP, 90541SSA, 90501SQH, 90851TFJ, 91191U4R, 91391UI0, 90751T73, 91391UHQ, 90771T9L, 90851TFL			Soft Tissue Biopsy Needle Core	Ila	12734	Needle, biopsy, general purpose, single-use
PRO-MAG BIOPSY NDL	765014100, 765014120, 765016100, 765018100	90551SU0, 90551SU1, 90611SYJ, 90761T8Y, 90771TAH, 90781TBL, 90831TDY, 90911TK9, 91121TWT, 91271UA6, 91341UET, 91391UHN, 91481UNX, 91491UPN, 91661V0I, 91691V3D, 91761V94, 90541SSM, 90551STX, 90681T3H, 90701T58, 91171U1C, 91321UAQ, 91481UNY, 91821VDX, 90751T7Z, 90831TDW, 90991TR4, 90991TR5, 91031TR6, 91321UB8, 91661V0O, 90481SO1, 90621T04, 90621T05, 90901TJ7, 91121TY1, 91131U0J, 91171U1V, 91381UH2	K980226	II		Ila	12734	Needle, biopsy, general purpose, single-use

EU PRODUCT LIST

Product	Part Number	Lot Numbers	510(k)	Class	Description	MDD Class	GMDN Code	GMDN Term
TRU-CORE BIOPSY NEEDLE	763314100, 763316100, 763318100	90541SRD, 90611SXP, 90981TQ5, 90971TNX, 90971TO1	K990839	II		Ila	12734	Needle, biopsy, general purpose, single-use
ULTRACORE BIOPSY NEEDLE	762614100, 762614130, 762616100, 762616130, 762618100	90551STO, 90681T40, 90821TCS, 90901TIY, 90911TK8, 91261U8B, 91261U8C, 91271U9A, 91381UGH, 91821VDG, 91821VDH, 91821VDI, 91821VDJ, 90771TA7, 90781TB2, 91181U2M, 90501SQI, 90921TKO, 90761T8U, 90901TIN, 91181U32, 91401UJ9, 91741V7S	K921418	II		Ila	12734	Needle, biopsy, general purpose, single-use
MANAN SACN BIOPSY NEEDLE	SACN1608MF, SACN1808MF	91271U9J, 90681T31	K980226	II		Ila	12734	Needle, biopsy, general purpose, single-use
CHIBA NEEDLE	MCN1803, MCN1806, MCN2003, MCN2006, MCN2203, MCN2206, MCN1803US, MCN1806US, MCN2006US, MCN2203US, MCN2206US	90771T9S, 90821TCE, 90611SY0, 90921TKX, 91601UWP, 90551STK, 90751T7E, 90971TNP, 91271U9Q, 91801VC3, 90751T80, 90781TB3, 91271U9M, 91341UF6, 90771T9V, 91051TTV, 91171U1X, 91341UFL, 90701T5D, 90541SSB, 90701T5F, 90981TQJ, 90991TR3, 91131TZE, 90681T3J, 90751T6Z, 91131TZ2, 90481SNX, 90751T7F, 90751T7G, 90751T7H, 90821TCB, 91391UIE, 91561UTN, 91561UTO, 91561UTP, 91561UTQ, 91561UTR, 91741V7Q, 90571SUO, 90751T77, 90961TM8, 91131TZC	K980122	II	Soft Tissue Biopsy FNA (Fine Needle Aspiration)	Ila	12734	Needle, biopsy, general purpose, single-use
SPINAL NEEDLE	MSPN2003US, MSPN2006, MSPN2203, MSPN2203US, MSPN2206, MSPN2206US	90911TK4, 90821TCL, 90981TQ1, 90611SY4, 91271U9H, 91531UQQ, 90891TH5, 90921TKP, 90971TOM, 91121TXV, 91181U31, 91821VDO, 91531UQM, 91801VCA				Ila	12734	Needle, biopsy, general purpose, single-use
TROCAR NEEDLE	MTN1806	91271U9K				Ila	12734	Needle, biopsy, general purpose, single-use
WESTCOTT NEEDLE	MWN2003, MWN2006, MWN2203, MWN2206, MWN2003US, MWN2006US, MWN2203US, MWN2206US	90751T5J, 90891TGT, 90981TPQ, 90971TNT, 91401UJE, 90571SVZ, 90921TKV, 90641T2R, 90631T11, 90781TBD, 91121TY4, 91171U1Q, 91181U2K, 91591UUF, 90971TNN, 91111TW3, 91471UNK, 90891TGU, 91311UBD, 90901TIM, 91671V1O				Ila	12734	Needle, biopsy, general purpose, single-use
FRANSEEN NEEDLE	MFN1803, MFN1806, MFN2003, MFN2006, MFN2203, MFN2206, MFN1803US, MFN2203US	91191U3Z, 90751T72, 91401UJ2, 90901TIS, 91181U2Q, 91331UCN, 91041TSZ, 90571SWD, 90781TB5, 91601UWS, 90701T5B, 90971TNV, 91311UBA, 91191U3X, 91621UZ6, 90541SSL, 90971TNS, 91131U0A				Ila	12734	Needle, biopsy, general purpose, single-use
GREENE NEEDLE	MGN2206X	90751T70, 91191U40				I	12734	Needle, biopsy, general purpose, single-use
MAXI-CELL BIOPSY NDL W/INTRO-ECHO	MMC2203US	91111TX4	K021847	II		Ila	12734	Needle, biopsy, general purpose, single-use
MAXI-CELL BIOPSY NEEDLE	MMC2202, MMC2203, MMC2203US, MMC2206, MMC2206US	90771T9P, 90771T9Q, 90641T1T, 90981TPR, 90771TAU, 90981TQF, 91381UGW, 91131U0B	K021847	II		Ila	12734	Needle, biopsy, general purpose, single-use
POTTS/COURNAND NEEDLE	MPCN1802	90821TCC	K974745	II		Vascular Access Needle	Ila	45018
SELDINGER NEEDLE	SN1802, SN1902	90621SZO, 90981TPN, 91311UB7, 91391UHR, 90621T00, 91201U63, 91541URU			Ila		45018	Needle Guide
BONE MARROW NEEDLE	ION18015	90571SUX, 90761T80, 91131TZQ	K980196	II	Bone Biopsy	Ila	46350	Needle, biopsy, bone marrow, single use

EU PRODUCT LIST

Product	Part Number	Lot Numbers	510(k)	Class	Description	MDD Class	GMDN Code	GMDN Term
GALACTOGRAPHY KIT	DGK002SX, DGK002X	90621T02, 90851TFY, 91681V2D, 91731V67, 90621SZZ, 90851TFZ, 91061TUL, 91201U4P, 91671V1I	K980227	II	Injection Media Contrast Kit Needle	Ila	16833	Biopsy kit, bone marrow
HAWKINS BLUNT NEEDLE	216057, 216107, 218057, 218107, 218157	90851TFD, 91131TZ5, 90571SUT, 91041TT1, 91401UJV, 90821TC4, 90821TC5, 90831TDL, 90961TMO, 91131TZG, 91131U0E, 91331UCU, 90621TOB, 90631TOV, 90761T8P, 90921TKS, 90921TKT, 90961TMO, 91131TY3, 91201U5R, 91271U9U, 91331UCT, 91461UMS, 91821VDN	K881957	I	Access Needle	Ila	45018	Needle Guide
INTRODUCER NEEDLE	BGWI1802, BGWI1902, GWI1802, GWI1802WW, GWI1902, GWI1902WW	90471SM2, 90541SRA, 90681T3G, 90751T6V, 91031TS5, 91331UBZ, 90751T79, 90751T7A, 90481SNV, 90541SRC, 90571SUN, 90621SZK, 90771T9K, 90821TCF, 90851TFK, 90901TIR, 90971TOS, 91041TST, 91041TSU, 91271U9B, 91311UAU, 91311UAV, 91311UAW, 91341UEW, 91341UEX, 91531UQI, 91531UQJ, 91621UZ1, 91631UZK, 90471SMB, 90541SS8, 90751T7J, 90841TEF, 90971TO5, 91181U2P, 90781TBC, 90831TE6, 91031TSI, 90851TFF	K974745	II		Ila	45018	Needle Guide
INTRODUCER SHEATH NEEDLE	ISN1915	90551STL, 91381UGK, 91891VI3, 91891VI4, 91891VI5	Exempt	I		Ila	45018	Needle Guide
COAXIAL NEEDLE	MCXS1408SX, MCXS1409LX, MCXS1410AX, MCXS1410MX, MCXS1410TX, MCXS1412SX, MCXS1415LX, MCXS1416AX, MCXS1609LX, MCXS1610AX, MCXS1610TX, MCXS1612SX, MCXS1615LX, MCXS1616AX, MCXS1616MX, MCXS1616TX, MCXS1808SX, MCXS1809LX, MCXS1810AX, MCXS1810TX, MCXS1812SX, MCXS1815LX, MCXS1816AX, MCXS1816MX, MCXS1816SX, MCXS1816TX, MCXS1820AX, MCXS1820LX, MCXS2009LY, MCXS2010AY, MCXS2010MY, MCXS2010TY, MCXS2012SY, MCXS2015LY, MCXS2016AY, MCXS2016MY, MCXS2016SY, MCXS2016TY	90471SMA, 90481SNT, 90481SNW, 90541SS3, 90541SSP, 90551STJ, 90571SUL, 90571SWE, 90611SXU, 90611SYF, 90621SZM, 90631T14, 90681T3U, 90691T4N, 90701T59, 90701T5E, 90701T5K, 90751T6W, 90751T71, 90751T76, 90751T78, 90751T7C, 90751T7I, 90751T7N, 90751T88, 90761T8H, 90761T8L, 90761T8M, 90761T8S, 90771TAS, 90781TB6, 90821TD1, 90831TDR, 90831TE7, 90891TFE, 90891TGQ, 90901TIG, 90901TIH, 90901TIQ, 90921TL2, 90961TM44, 90961TM7, 90971TNE, 90971TO2, 90971TOO, 90971TOQ, 90971TOR, 90981TPS, 90981TQG, 90991TNF, 90991TR1, 90991TR2, 90991TRD, 91031TRZ, 91041TSX, 91041TSY, 91111TWA, 91111TWG, 91131TZ6, 91131TZF, 91131U09, 91131U0G, 91131U0O, 91171U24, 91181TW1, 91181U33, 91181U34, 91181U35, 91191TW4, 91191TW6, 91191U44, 91191U45, 91191U4Q, 91201U5M, 91201U5N, 91271U9N, 91271U9W, 91331UCO, 91341UF4, 91401UIU, 91401UIZ, 91401UJ4, 91401UJA, 91401UJH, 91401UJQ, 91401UJU, 91471UNN, 91481UO8, 91481UOD, 91491UP9, 91531UQK, 91561UUH, 91591UV7, 91631UZI, 91681V2F, 91681V2G, 91681V2H, 91681V2P, 91731V61, 91741V7R, 91761V9C, 91761V9Q, 91801VCB, 91801VCC, 91801VCD, 91801VBM	K980004	I		Ila	45018	Needle Guide

EU PRODUCT LIST

Product	Part Number	Lot Numbers	510(k)	Class	Description	MDD Class	GMDN Code	GMDN Term
COAXIAL NEEDLE - BIOPINCE	MCXS1610BP, MCXS1615BP, MCXS1810BP, MCXS1815BP, MCXS1820BP	90551STY, 90551STZ, 90571SWG, 90611SXI, 90641T15, 90701T5L, 90751T7M, 90751T7P, 90781TBG, 90781TBU, 90851TFI, 90921TL5, 90961TM9, 90971TOT, 90981TQ3, 91041TQ2, 91271U9D, 91271U9E, 91331UC8, 91331UCG, 91331UCS, 91341UEP, 91341UFI, 91561UTV, 91611UYB, 91701V4Q, 91701V4R, 91801VCE				Ila	45018	Needle Guide
PROSTATE STABILIZATION SET	500118200	90571SV8, 90611SYC, 90681T44, 90821TCX, 90831TDV, 90841TEJ, 91191U4O, 91391UHV, 91421ULN, 91421ULO, 91541USO, 91611UYL, 91621UZB	K944522	II	Stabilization	Ila	38426	Brachytherapy applicator, manual, prostate
SKATER CENTESIS CATHETER	700304007, 700304010, 700304015, 700305007, 700305010, 7003015	90571SVY, 91041TT2, 90851TFB, 91131TZ8, 90571SVR, 90571SVS, 90681T3R, 90681T3S, 90821TCR, 90981TQ8, 91201U5V, 90681T3B, 90681T3C, 90681T3D, 90771TA4, 90971TOF, 91041TT4, 91131TZX, 91491UP0, 91491UP1, 90611SY6, 91051TTQ, 91131TZV	Exempt	I	Drainage Catheter	Ila	40601	Catheter, intravascular, general-purpose
LORAD NEEDLE GUIDE	LNGC14GX, LNGC1619PX, LNGC2022YX, LNGO1619PX, LNGO2022YX	90541SRM, 90781TB4, 91061TUF, 91121TTY, 90771T9M, 90781TBE, 90981TQE, 91061TUD, 91181U2N, 91391UHZ, 91771VAV, 90851TFH, 90821TBB, 91131TYY	Exempt	I	Needle Guide	I	12734	Needle, biopsy, general purpose, single-use