Public Citizen

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Joan Claybrook, President

July 6, 1995

Dr. David Kessler
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

We are writing to request that you immediately initiate a recall of tens of thousands of hazardous Becton Dickinson containers for used needles and syringes (sharps collectors) from hospitals and other medical facilities, and that you undertake a full investigation into the serious lapses in quality assurance at Med-Safe Systems, Inc., Becton Dickinson's supplier, that resulted in the production of these adulterated devices.[1] In addition, we urge you to initiate criminal prosecution of Med-Safe for withholding important safety information from the Food and Drug Administration (FDA).

Sharps collectors are plastic containers used to collect and dispose of potentially infectious used needles, syringes and other medical supplies. Between August and December 1994, Med-Safe (Oceanside, CA) knowingly produced for Becton Dickinson (Franklin Lakes, NJ) approximately half a million sharps collectors that fell as much as 45% below the specifications for minimum wall thickness that Med-Safe had guaranteed the FDA it would achieve. After a Med-Safe employee notified Becton Dickinson of Med-Safe's gross production irregularities, Becton Dickinson returned unused sharps collectors from this period to Med-Safe, but failed to recall those that had already been shipped to its customers. Consequently, tens of thousands of these dangerous sharps collectors are in use in hospitals and clinics across the country today, posing the risk of HIV, hepatitis B, hepatitis C, and other infections to health care workers and others who incur a needlestick injury from a syringe that protrudes through the substandard walls of these collectors. This incident underscores the need for more stringent regulation of medical

[1] According to the Centers for Disease Control and Prevention, each year workers suffer approximately 800,000 needlesticks, about 120,000 or 15% of which are related to needle/syringe disposal. Of the 800,000 workers who are stuck with needles each year, there are 12,000 instances in which they contract hepatitis B, with between 200 and 300 fatalities a year. In addition, through December, 1994, there were 42 proven instances in which a health care worker became infected with the AIDS virus because of their occupational exposure.

devices and illustrates the dangers of the deregulatory measures currently under consideration, which would increase the likelihood of similar problems occurring.

Production of and Failure to Recall Unsafe Sharps Collectors

For almost four years, Med-Safe has been under contract with Becton Dickinson to produce a 5.4 quart sharps collector known as the Guardian. There are two versions of the Guardian, one in which needles and syringes are inserted horizontally ("horizontal entry") and another in which they are introduced from the side ("side entry"). Both use the same polypropylene base, known within Med-Safe as the 1020B. On August 3, 1994, Med-Safe filed a marketing notification with the FDA under section 510(k) of the Food, Drug, and Cosmetic Act stating that the minimum acceptable wall thickness for the Guardian was 0.050 inches (1/20 of an inch) (see Attachment 1). As you know, manufacturers of sharps collectors are required to submit 510(k) notifications, which describe the device in detail and outline quality assurance procedures to establish the safety and efficacy of their products. Sharps collector wall thickness is a critical component of quality assurance as it is closely correlated with needle puncture resistance.

It was around this time that the 1020B sharps collector base began to consistently fail to meet the minimum wall thickness specification. (Wall thickness had been dropping throughout 1994 and was frequently below specification.) Each time the production process was substantially altered, Med-Safe operating procedures required that the wall thicknesses of the first two and last two 1020B bases in that production line be determined. The results from these First and Last Shot Reports were as follows: on August 29 the two bases had wall thicknesses of 0.042 and 0.0475 inches, on September 9 the thicknesses were 0.0427 and 0.0524 inches, on October 1 they were 0.040 and 0.048 inches, and on October 6 they were 0.042 and 0.047 inches (see Attachment 2). The 0.040 inch base was 20% thinner than required by the specifications. These were manufactured under an internal "deviation" issued on August 8, 1994 that expired on September 15, 1994. The deviation was issued by Med-Safe's Quality Assurance Director Virginia Shillington, wife of Med-Safe's Chairman and Chief Executive Officer, Richard Shillington. Becton Dickinson and the FDA were not notified at this time that the devices were consistently failing to meet the agreed-upon specifications.

On September 22, 1994, Med-Safe ordered all quality control inspectors to stop recording the results of In-process[2] inspections for four days (see Attachment 4); this illegal practice was continued without written authority and was Med-Safe practice through

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[2] In-process inspections were scheduled to occur every eight hours (as opposed to first and last shot inspections which occurred only when the production process changed substantially). One of these in-process inspections, dated September 15, 1994, shows base thicknesses of 0.039 and 0.037 inches (see Attachment 3).

at least mid-December 1994.[3] Again, neither Becton Dickinson nor the FDA was notified that important aspects of inspection documentation had been suspended.

On December 6, 1994, Med-Safe Quality Control Supervisor David Thielke reported at a quality assurance/production meeting that the minimum wall thickness was at times as low as 0.028 inches, about half the specification Med-Safe had promised Becton Dickinson and the FDA. It appears that Med-Safe wished to maintain its production schedule through January 1995, when a refurbished mold was expected to become available.

On December 20, 1994, after being notified by a Med-Safe employee about the serious production and inspection infractions at Med-Safe, Becton Dickinson returned about 125,000 unused Guardian sharps collectors stored in its warehouses. However, they failed to initiate a recall of the hazardous devices then in use or to notify the FDA (telephone conversation with John Samalik, FDA, April 12, 1995). Tens of thousands of these sharps collectors are still in use in U.S. hospitals and clinics, posing a risk of life-threatening needlestick injury to unsuspecting health care workers. Attachment 5 includes the lot numbers of the unsafe sharps collectors.

Evidence of Prior Production Problems at Med-Safe

The problems discussed above are nothing new. Production problems at Med-Safe predate the 1020B experience and involve additional lines of sharps collectors. As early as December 10, 1992 Med-Safe Quality Assurance Director Virginia Shillington and President Ralph C. "Buck" Dawson were informed of a variety of mold production problems, including wall thicknesses under the specified 0.050 inch minimum for seven Med-Safe sharps collectors, including an earlier version of the 1020B (see Attachment 6). These problems were essentially ignored by the company, which did not report them to Becton Dickinson or the FDA, and the wall thicknesses continued to be under specification.

On January 10, 1994, quality assurance officials from Med-Safe made an inspection of sharps collectors and other medical devices at a Becton Dickinson warehouse in Dacula, GA. The warehouse stores sharps collectors and blood collection kits made by another Med-Safe supplier, Constar International. Constar makes devices for Med-Safe using a different process called blow molding; Med-Safe then sells these to Becton Dickinson. This process produces a stronger wall, and consequently the minimum wall thickness requirement for blow-molded products is only 0.040 inches. The Med-Safe inspection documented that 93% of inspected devices fell below that specification (see Attachment 7). Again, neither Becton-Dickinson nor the FDA was notified.

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[3] The memorandum that suspended the recording of inspection results technically applied only to in-process inspections. However, except for a single inspection on October 6, 1994, recording of the First and Last Shot Inspections also appears to have been suspended as there were numerous changes in the production process after October 6, but no First and Last Shot Records exist for this period.

Misleading the FDA by Stating that Quality Assurance Tests Had Been Completed

Med-Safe's August 3, 1994 510(k) notification included claims that it had conducted a variety of quality assurance tests on a number of different sharps collectors and blood collection kits. However, on August 17, 1994, Timothy Ulatowski of the FDA's Office of Device Evaluation wrote to Med-Safe, noting that the results of a large number of these tests had not been submitted with the 510(k), and asked that Med-Safe provide the FDA with the test results. But a Med-Safe internal audit on August 29 revealed that a total of 153 tests on 27 different devices had never been conducted (see Attachment 8). The company had therefore misled the FDA by claiming that the tests had already been satisfactorily completed. This deliberate misleading of the FDA warrants criminal prosecution.

Conclusion

The internal company memos attached hereto reveal that Med-Safe has for several years exhibited a reckless disregard for the public health by producing dangerously thin-walled sharps collectors. It has sought to cover up its irresponsible behavior by eliminating the paper trail that would have demonstrated that the wall thicknesses fell below specifications. The company has misled the FDA by failing to report the substandard wall thicknesses and by stating that certain tests had been conducted when they had not. Becton Dickinson, upon being notified of these circumstances, returned unused sharps collectors but allowed tens of thousands of dangerous collectors to remain in use, placing the lives of health care workers throughout the country in danger.

Five years after Britain enacted a national standard for sharps collectors and three years after Australia followed suit, the FDA has yet to promulgate regulations governing these potentially hazardous devices. If the FDA takes its role in regulating medical devices seriously, it will issue these long-delayed regulations, promptly initiate an investigation into Med-Safe's illegal conduct, and require Becton Dickinson to immediately recall the sharps collectors currently in use. To do anything less, would be to continue to put health care workers at risk for HIV or hepatitis infection.

Sincerely,

Peter Lurie, MD, MPH
Research Associate
Health Research Group

Sidney M. Wolfe, MD
Director
Health Research Group

4.0 SPECIFICATIONS OF DESIGN FEATURES AND DESIGN VALIDATION TEST METHODS

As requested in section I and J of the guideline, Med-Safe Systems, Inc. meets the following specifications and Design Validation test methods:

4.1 Impact Resistance

Specification: Med-Safe Systems, Inc. GS-001

Test Method: Fill container 3/4 full with assorted Sharps items and needles attached to hypodermic syringes. Seal as if ready for final transport. Drop container 39" to the base on a hard surface floor.

Pass/Fail Criteria: No gross fractures (external wall of container is open enough to allow escape of solid contents) or loss of contents are permitted. Stress fractures (crack in external wall where wall parts do not separate to release solid contents) are permitted. This test is conducted on new designs or materials.

Impact Resistance Safety/Effectiveness:

If accidently dropped from a cart or counter height the Sharps collector should remain intact without exposing sharps to the Health Care Worker. The design and materials chosen for the construction of a Sharps collector shall be evenly balanced between puncture resistance and impact resistance.

4.2 Puncture Resistance

Specification #1: Med-Safe Systems, Inc. GS-001 based on proposed ASTM standard F04 65.01 for puncture resistance of sharps containers draft #16. This specification represents the overall average puncture resistance of a container. This test is conducted when a product is designed.

Test Method #1: From the sharps container, cut 12 samples each from the base, side walls, closure and the top, excluding the closure. Penetrate each sample using motorized penetration equipment (Instron, ATS or equivalent) with a new 21 gauge X 1" needle, each penetration at 4"/minute. Record initial puncture.

Pass/Fail Criteria #1: Averages of the forces shall be not less than 3.4 lbs. and the force needed to penetrate any one sample shall be not less than 2.8 lbs.

Specification #2: Med-Safe Systems, Inc. GS-001, test method based on ECRI Health Devices, August-September 1993, Vol.22 Nos.8-9, minimum forces based on BSI BS7320:1990 Specification for Sharps containers and proposed ASTM standard F04.65.01 for the puncture resistance of sharps containers draft #16. This test is conducted when the product is designed. See mapping photo, page 17.

Test Method #2: From each molded sharps container cavity, scan the wall thicknesses every inch and mark thickness of area on the product. Puncture the thinnest area scanned.

Pass/Fail Criteria #2: No wall less than 0.050" is acceptable.
No penetration less than 2.8 lbs is acceptable for the initial penetration force.

Puncture Resistance Safety/Effectiveness:

Med-Safe Systems, Inc. GS-001 has developed the puncture resistant testing to conform to the key elements of the BSI standard (BS7320:1990) and ASTM standard (F04.65.01). The force of a hypodermic needle (21 X 1 Gauge) is measured as the initial point penetrates the wall of the collector.

This force required is no less than an average of 3.4 lbs, with no one puncture less than 2.8 lbs. as required by the BSI and ASTM standards.

Med-Safe Systems, Inc.

Form 42 - FIRST AND LAST SHOT REPORT

NOTE: A First Shot Report is a post-setup inspection of certain qualitative and quantitative characteristics of all cavities of an injection molded part. First Shot inspection is used to ascertain critical part quality prior to beginning production of that part. With approved cavities, a production run may be approved to commence. Any production accumulated prior to approval must be quarantined. In no case may a First Shot Report be used as the sole inspection criteria to qualify and/or release any new or modified component of a medical device.

	First Shot	Last Shot
Inspector	THOMAS/ANTHONY	
Date/Shift	8-29-94 2ND	
Part No./Lot	1020-7 / 4HM06	/
Resin No.	SA 747M	
Colorant No.	PEARL	

INSPECTIONS Circle Accept/Reject or measure as indicated.	FULL SHOT Cav # 1	Cav # 2	Cav #	Cav#
VISUAL INSPECTION				
Cracks, splits, holes	(A) R	(A) R	A R	A R
Color dispersion	(A) R	(A) R	A R	A R
Bowing and/or sink	(A) R	(A) R	A R	A R
Dirt or grease	(A) R	(A) R	A R	A R
Contamination	(A) R	(A) R	A R	A R
Engravings	(A) R	(A) R	A R	A R
Short Shot	(A) R	(A) R	A R	A R
CAP OR PLUG FITMENT*	A N/A R	A N/A R	A R	A R
TOP-TO-BOTTOM FITMENT*	(A) R	(A) R	A R	A R
DOOR-TO-TOP FITMENT*	A N/A R	A N/A R	A R	A R
BRACKET FITMENT*	(A) R	(A) R	A R	A R
MAXIMUM FLASH (.xxx in)	.300 "	.150 "	. "	. "
MINIMUM WALL (.xxx in)	*.042 "	*.0175 "	. "	. "
GRAM WEIGHT (xx.x gm)	245.5 g	241.4 g	. g	. g
ACCEPT/REJECT CAVITY	(A) R	(A) R	A R	A R

* Parts must be cured at least 4 hours at room temperature.

COMMENTS: * REF NCR# 78
≥.043

APPROVED
OM 8/30/94

Med-Safe Systems, Inc.

Form 42 - FIRST AND LAST SHOT REPORT

NOTE: A First Shot Report is a post-setup inspection of certain qualitative and quantitative characteristics of all cavities of an injection molded part. First Shot inspection is used to ascertain critical part quality prior to beginning production of that part. With approved cavities, a production run may be approved to commence. Any production accumulated prior to approval must be quarantined. In no case may a First Shot Report be used as the sole inspection criteria to qualify and/or release any new or modified component of a medical device.

	First Shot	Last Shot
Inspector	THOMAS	
Date/Shift	9.9.94 / 3RD	
Part No./Lot	1020-3 / 4JM02	/
Resin No.	SA 747m	
Colorant No.	NAT.	

INSPECTIONS Circle Accept/Reject or measure as indicated.	FULL SHOT			
	Cav # 1	Cav # 2	Cav #	Cav#
VISUAL INSPECTION				
Cracks, splits, holes	(A) R	(A) R	A R	A R
Color dispersion	(A) R	(A) R	A R	A R
Bowing and/or sink	(A) R	(A) R	A R	A R
Dirt or grease	(A) R	(A) R	A R	A R
Contamination	(A) R	(A) R	A R	A R
Engravings	(A) R	(A) R	A R	A R
Short Shot	(A) R	(A) R	A R	A R
CAP OR PLUG FITMENT*	A R	A R	A R	A R
TOP-TO-BOTTOM FITMENT*	A R	A R	A R	A R
DOOR-TO-TOP FITMENT*	(A) R	(A) R	A R	A R
BRACKET FITMENT*	A R	A R	A R	A R
MAXIMUM FLASH (.xxx in)	.200 "	.150 "	. "	. "
MINIMUM WALL (.xxx in) *	(.0427 "	.0524 "	. "	. "
GRAM WEIGHT (xx.x gm)	243.5 g	239.5 g	. g	. g
ACCEPT/REJECT CAVITY	(A) R	(A) R	A R	A R

* Parts must be cured at least 4 hours at room temperature.

COMMENTS: * Ref. NCR # 78

APPROVED
D. M. 9/23/94

Med-Safe Systems, Inc.

Form 42 - FIRST AND LAST SHOT REPORT

NOTE: A First Shot Report is a post-setup inspection of certain qualitative and quantitative characteristics of all cavities of an injection molded part. First Shot inspection is used to ascertain critical part quality prior to beginning production of that part. With approved cavities, a production run may be approved to commence. Any production accumulated prior to approval must be quarantined. In no case may a First Shot Report be used as the sole inspection criteria to qualify and/or release any new or modified component of a medical device.

	First Shot	Last Shot
Inspector	LIVIA	
Date/Shift	10/01/94 1ST	
Part No./Lot	1020-7 / 4KM01	/
Resin No.	SA747M	
Colorant No.	RED	

INSPECTIONS Circle Accept/Reject or measure as indicated.	FULL SHOT Cav # 1	Cav # 2	Cav #	Cav#
VISUAL INSPECTION				
Cracks, splits, holes	(A) R	(A) R	A R	A R
Color dispersion	(A) R	(A) R	A R	A R
Bowing and/or sink	(A) R	(A) R	A R	A R
Dirt or grease	(A) R	(A) R	A R	A R
Contamination	(A) R	(A) R	A R	A R
Engravings	(A) R	(A) R	A R	A R
Short Shot	(A) R	(A) R	A R	A R
CAP OR PLUG FITMENT*	AN/A R	AN/A R	A R	A R
TOP-TO-BOTTOM FITMENT*	AN/A R	AN/A R	A R	A R
DOOR-TO-TOP FITMENT* AFTER 24 HOURS	(A) R	(A) R	A R	A R
BRACKET FITMENT*	(A) R	(A) R	A R	A R
MAXIMUM FLASH (.xxx in)	.300"	.130"	. "	. "
MINIMUM WALL (.xxx in)	*(.040)"	*(.048)"	. "	. "
GRAM WEIGHT (xx.x gm)	244.1 g	239.8 g	. g	. g
ACCEPT/REJECT CAVITY	A R	A R	A R	A R

* Parts must be cured at least 4 hours at room temperature.

COMMENTS:

* Ref. NCR #78

APPROVED
OM 10/02/94

FORM42.B (8-18-94)

Med-Safe Systems, Inc.

Form 42 - FIRST AND LAST SHOT REPORT

NOTE: A First Shot Report is a post-setup inspection of certain qualitative and quantitative characteristics of all cavities of an injection molded part. First Shot inspection is used to ascertain critical part quality prior to beginning production of that part. With approved cavities, a production run may be approved to commence. Any production accumulated prior to approval must be quarantined. In no case may a First Shot Report be used as the sole inspection criteria to qualify and/or release any new or modified component of a medical device.

	First Shot	Last Shot
Inspector	Ali Del	
Date/Shift	10/6/94	
Part No./Lot	1020-3 / 4KM02	/
Resin No.	SA-747M	
Colorant No.	NATURAL	

INSPECTIONS Circle Accept/Reject or measure as indicated.	FULL SHOT Cav # 1	Cav # 2	Cav #	Cav#
VISUAL INSPECTION				
Cracks, splits, holes	(A) R	(A) R	A R	A R
Color dispersion	(A) R	(A) R	A R	A R
Bowing and/or sink	(A) R	(A) R	A R	A R
Dirt or grease	(A) R	(A) R	A R	A R
Contamination	(A) R	(A) R	A R	A R
Engravings	(A) R	(A) R	A R	A R
Short Shot	(A) R	(A) R	A R	A R
CAP OR PLUG FITMENT*	A N/A R	A N/A R	A R	A R
TOP-TO-BOTTOM FITMENT*	A N/A R	A N/A R	A R	A R
DOOR-TO-TOP FITMENT* (1021-3 1019-3 AFTER 24 HRS.)	(A) N/A R	(A) R	A R	A R
BRACKET FITMENT*	(A) R	(A) R	A R	A R
MAXIMUM FLASH (.xxx in)	.195 "	.050 "	. "	. "
MINIMUM WALL (.xxx in)	*(.042) "	*(.047) "	. "	. "
GRAM WEIGHT (xx.x gm)	242.2 g	238.6 g	. g	. g
ACCEPT/REJECT CAVITY	(A) R	(A) R	A R	A R

* Parts must be cured at least 4 hours at room temperature.

COMMENTS:

Ref. NCR# 78
expired 9/15/94

APPROVED
(QM) 10/27/94

QUALITY CONTROL PRODUCTION TESTING
Form 44 IN-PROCESS INSPECTIONS
System III BASE - #1020 □ A ~~□~~ B (Check one)

Date	9-15-94	QA Inspector	THOMAS
Shift/Machine	3rd/No. 12	Mfg Lot No.	4JM02
Cycle Time/Resin	26.13/SA747M	Color	(N) R Y P

Sample No.	#1	#2	#3	#4
Cavity No.	1	2	1	2
Time Molded	03:00	03:20	:__	__:__

HOURLY FLAG Measurement: Refer to target flag measurements; record on back pag

WEIGHT: Record on back page

VISUAL:

Flash or string	A	A		
Cracks, marks ...	A	A		
Color/Dispersion	A	A		
Texture/bubbles	A	A		
Dirt or grease	A	A		
Waves/sink	A	A		
Contamination	A	A		
Flow lines	A	A		
Short shots	A	A		
Scratches	A	A		

WALL: .050"/.060"

Minimum	* 0.0590"	* 0.037"	0.0___"	0.0___"

FLAG Measurement: Refer to chart of target flag measurements. FLAG 10.050 Iors"

Width: After 24 hours	10.048"	10.051"	10.0___"	10.0___"

FORM, FIT, & FUNCTION (Go/No Go after 24 hours using 3cc thru 60cc syringes in B-D Bracket (B) and Sage Bracket (S). Use a Phase 1 subassembly and install to base):

Test with #1019 lot 4JM01 #1021 lot 4HN01

	Performance Results								
Syringe	#1B	#1S	#2B	#2S	#3B	#3S	#4B	#4S	FAILURE MODE LEGEND
3cc	P	P	P	P	___	___	___	___	NO - Door did not open
5cc	P	P	P	P	___	___	___	___	NR - Door did not return
10cc	P	P	P	P	___	___	___	___	P - Door opened & closed
20cc	P	P	P	P	___	___	___	___	PO - Door partially opened
30cc	P	P	P	P	___	___	___	___	PR - Door partially returned
60cc	P	P	P	P	___	___	___	___	SR - Door has slow return
Go/NoGo	Go	Go	Go	Go	___	___	___	___	

COMMENTS:
* NCR # 78

APPROVED
QC 9/19/94

September 22, 1994

MEMORANDUM

TO: GINNY SHILLINGTON
DIRECTOR OF QUALITY ASSURANCE

FROM: DAVID THIELKE
QUALITY CONTROL SUPERVISOR

SUBJECT: CANCELLATION OF PHYSICAL RECORDING ON DAILY IN-PROCESS INSPECTION SHEETS

Starting Thursday, 9/22/94 thru 9/25/94, all Q.C. inspectors will stop physical recordings and form, fit and functions on daily In-Process Inspection sheets. This is being implemented so that Q.C. inspectors can devote time to floor inspections and to training the newly hired production workers. Finished goods inspections will continue to be documented as specified.

This change will also serve as a basis for possible elimination of In-Process Inspections once Process Validation has been completed.

Attach a copy of this memorandum to each daily Finished Goods Inspection Sheet.

Distributor: Becton Dickinson, 1 Becton Drive, Franklin Lakes, NJ

Potentially Unsafe Sharps Collectors Becton Dickinson GUARDIAN Point-of-Use 5.4 Quart Capacity					
Reorder No.	August 1994	September 1994	October 1994	November 1994	December 1994
	Lot Numbers of 12-Pack Horizontal Entry preassembled models				
305426	4HM01				
305427					4MM01
305428		4JM01			4MM01
	Lot Numbers for 12-Pack Side Entry preassembled models				
305425		4JM01 4JM02			
300474	4HM01				
300475	4HM01		4KM01 4KM02		4MM01
	Lot Numbers for 20-Pack Horizontal Entry semiassembled models				
305445	4HM01 4HM02 4HM03	4JM01	4KM01 4KM02 4KM03 4KM04		
305446	4HM01	4JM01 4JM02 4JM03	4KM01 4KM02		
305452	4HM01 4HM02 4HM03	4JM01 4JM02 4JM03 4JM04	4KM01 4KM02 4KM03	4LM01 4LM02 4LM03	4MM01 4MM02 4MM03
	Lot Numbers for 20-Pack Side Entry semiassembled models				
305443	4HM01 4HM02 4HM03		4KM01 4KM02		
305444	4HM01 4HM02 4HM03	4JM01 4JM02 4JM03 4JM04 4JM05 4JM06	4KM01	4LM01 4LM02 4LM03 4LM04 4LM05 4LM06	

December 10, 1992

TO: Buck and Ginny

FROM: Steve Steve

CC: Alec David Dick Erhardt Gil
Jeff Masood

SUBJECT: Current Quality Problems with Intermed Plastics Mold and/or Processes

The following injection mold parts/processes have been documented to show defects as itemized below. Some of these defects are minor and some are major, but all are defects that do not meet current QA current specifications.

The continual "monitoring" of these defects complicates the ongoing inspection process by undermining the seriousness of QA specifications. It also places added responsibility on inspectors to continually monitor known production defects. IPI should have deviations from the specifications per our own specifications.

We need to discuss each defect and decide how to address each one in light of Med-Safe priorities, specifications, production schedules, maintenance schedules, and customer needs. This list was compiled to give us an idea about the extent of the defects and to give us a starting point.

Contamination:

#1016 Yellow PUDs (.020" specks)
#1017 Guardian Front (.030" specks)
#1018 Guardian Back (.035" specks)
#1020 Pearl Bases (.025-.030" specks)
#1013 Yellow 14-Qt. Bottom (.045" specks)

Underspec Wall Thickness:

#1013 14-qt. Bottom (.049" bottom corner)
#1014 6-gal Bottom (.039" bottom corner)
#1019 Phase 1 Top (.031/.034" gate area Cavity1/2)
#1020 Base (.044/.041" back left-side corner Cavity 1/2)
#1021 Phase 1 Door (.038" finger grip)
#1025 Phase 2 Top (.044/.043" leftside/rightside Cavity1/2)
#1026 Phase 2 Door (.041/.042" leftside (Cavity 1/2)

Intermittent Core Shifts:

#1014 6-gal Bottom
#1011 8-qt Bottom
#1020 Base

January 17, 1994

TO: Ginny

FROM: Steve

SUBJECT: Trip Report for Atlanta, GA -- January 9-12, 1994

General Product Audit at B-D Dacula Warehouse - January 10

I performed a general product audit at Dacula. I am pleased to report a very high level of general quality found in all Med-Safe products. I inspected one carton of 25 different products and I found only minor problems such as product labels still lifting or tunneling, supplier pallet tags inadvertently attached, and slightly abraded cartons from transit friction. One carton of #305487 3MS01 did not have a carton lot stamp and its #1005-1 caps were incorrectly installed with the final closures off the opposite label sides (12-23-93 Constar Shift 2 and verbally communicated to QC Supervisor).

Dacula reported the following items of interest.

1. Obsolete sharps products still in inventory (no recent orders):
   Florida stock - 5 pallets
   4-digit stock - 14 pallets

   Products and lot were recorded for later disposition by Med-Safe.

2. 42 cartons of #305447 were reported damaged in transit due to bottom carton crushing on pallets with wide-spaced slats. Med-Safe QA was aware of this problem and is conducting relevant stacking and shipping testing. The carton appears adequate if palletized properly for transit.

3. One warehouse personnel was struck in the head with a carton of 5-Gallon product when removing it off the top layer. General compliant is that top 5-gallon cartons are too high, too cumbersome, and too heavy.

Audit of Constar Products in Dacula Warehouse - January 10

I specifically inspected sharps products from Constar for gram weight and minimum wall thickness; detail results are shown on page 2. In summary, these results show the following quality performance:

SUMMARY OF CONSTAR QUALITY PERFORMANCE		
PERFORMANCE CATEGORY	GRAM WEIGHT FREQUENCY	MINIMUM WALL FREQUENCY
Under spec	36%	93%
Within spec	50%	7%
Over spec	14%	0%

SD-45200
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MEASUREMENT RESULTS OF CONSTAR PRODUCTS								
Product	Test Sample		Gram Weight			Minimum Wall		
	Catalog	Cavity	Spec	Actual	P/F	Spec	Actual	P/F
Vacutainer	367201 3MS01	5	80±5g	85g	P	.040"	.037" FILL LINE CORNER	F
		6		85g	P		.034" UPPER CORNER	F
		7		90g	F		.029" LOWER CORNER	F
		8		90g	F		.029" LOWER CORNER	F
1.4 Quart	305487 3MS01	11	135±5g	118g	F		.037" BOTTOM CORNER	F
		12		128g	F		.040" BOTTOM CORNER	P
		13		128g	F		.034" BOTTOM CORNER	F
		14		133g	P		.038" BOTTOM CORNER	F
6.9 Quart	305489 3KS02	11	310±10g	288g	F		.030" UPPER CORNER	F
		12		303g	P		.030" LOWER CORNER	F
8 Quart	305490 3LS04	11	355±10g	353g	P		.036" UPPER CORNER	F
		12		348g	P		.031" LOWER CORNER	F
9.2 Quart Chemo Offset Neck	305478 3JS01	NA	435±20g	408g	F		.036" UPPER SIDE WALL	F
5 Gallon	305491 3KS02	NA	745±20g	765g	P		.025" LEFT HANDLE	F

ATTACHMENT 8

STATUS OF 510K DESIGN VALIDATION TESTING

Sharps Collector Category (Issue)	510K Test Results on File as of 8-29-94	Testing and Results Still Required							
		Overfill	Leak	Closure	Stable	Accy	Handle	Capacity	Aero
Insulin Home Sharps (resin)	QA327-1, QA246, QA324, QA292	x			x	x	x	x	x
SysIII HD (2 base versions)	QA258-1, QA271, QA205, QA241, QA325	x	x	x	x		x		x
SysIII SE (2 base versions)	QA258-1, QA262, QA205, QA241, QA325	x	x	x	x		x	x	x
PUD w/o handle	QA299, QA273, QA399, QA325	x	x	x	x	x			x
PUD w/ handle	QA52-2, QA352-3, QA325	x		x	x				x
8-QT Nestable	QA258, QA304, QA361, QA197, QA325	x	x	x	x				x
14-QT Nestable	QA258, QA303, QA363, QA325	x	x	x	x	x			x
6-GAL nestable	QA258, QA272, QA287, QA363, QA325	x	x	x	x	x			x
VACUTAINER 7266 (need impact test)	QA286	x	x	x	x	x	x	x	x
VACUTAINER 7201	QA298, QA258, QA286	x	x		x	x		x	x
1-QT mailback	QA283, QA325, UST107159-4	x			x	x	x		x
3.3-QT mailback	QA273, QA325 UST107159-6	x			x	x	x		x
8-QT mailback	QA376, QA281, QA364, QA325, UST107159-2	x			x	x	x		x
8-QT mooback	QA307, QA281, QA325, UST111357	x			x	x	x		x
5-GAL mailback	QA282, QA325, UST107159-3	x			x	x	x		x

STATUS OF 510K DESIGN VALIDATION TESTING

Sharps Collector Category (issue)	510K Test Results on File as of 8-29-94	Testing and Results Still Required							
		Overfill	Leak	Closure	Stable	Accy	Handle	Capacity	Aero
6.9-QT chemo	QA259, QA278, QA325	x	x	x	x	x	x		x
9.2-QT chemo	QA259, QA284, QA325	x	x	x	x	x	x		x
5-GAL chemo	QA259, QA280, QA325	x	x	x	x	x	x		x
.7-QT phlebo	QA259, QA274	x	x	x	x	x		x	x
1-QT snap-on (need impact test)	QA276, QA217	x	x	x	x	x	x		x
1.4-QT one-piece	QA343								x
1.4-QT BDCP (need impact and puncture)	QA343			x			x		x
3.3-QT one-piece	QA344								x
6.9-QT one-piece	QA259, QA278, QA325	x	x	x	x	x	x		x
8.2-QT one-piece	QA259, QA279, QA325	x	x	x	x	x	x		x
5-GAL one-piece	QA259, QA280, QA325	x	x	x	x	x	x		x
9.2-QT one-piece	QA259, QA284, QA325	x	x	x	x	x	x		x