



URGENT FIELD SAFETY NOTICE:
INSTRUCTIONS TO END USER

Commercial Name: Unomedical Sterile Urine Drainage Bags
LOT No: Please see attached sheet for reference numbers & affected LOT numbers
FSCA Id: 2010/11 URI
Type of action: Return of product to supplier

26th November 2010

Description of the problem:

Unomedical would like to inform you of a potential manufacturing irregularity during the production of certain units of Unomedical urine drainage bags (sterile leg bags (350, 500 and 750ml), sterile 2l night bags (including systems pre-connected to Foley catheters) and sterile 4l irrigation bags - a complete list of affected product is attached). In certain units, there is potential that the connector between the catheter and the bag may be blocked. If this were to occur, urine would not drain into the bag which may result in urine retention in the bladder. Urine retention may necessitate medical intervention additional to routine care. The bag would need to be changed more often and the risk of developing an infection if standard of care were neglected may increase.

To address any potential risk of harm, the affected product (which may be identified by the lot numbers using the identification procedure specified below) is being recalled.

This recall covers the lot numbers as specified in the attached sheet.

Identification Procedure

Other than product lot number, there is no discernable difference between the packaging of the recalled product and unaffected product. The lot number can be found on the carton, box, and the individual peel pack/pouch.

If the lot number is not available, the recalled product cannot be identified through visual inspection. It can only be identified through testing prior to use.

Instruction on action to be taken by the End User:

Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please stop the use of all products from the affected LOTs, which you may have.
2. Check stock and complete the enclosed form which should be forwarded to your distributor by 31st January 2011.
3. Return all affected products to your distributor for credit by 31st January 2011.
4. Please mark all returned product clearly with: "Unomedical Urine Drainage Bags Recalled Products from Your Name Here"

Transmission of this Field Safety Notice:

Unomedical apologises for any inconvenience this may cause and requests that you share this Notice with all relevant urine drainage bag customers/users. If you have any questions, please contact your distributor or local Unomedical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Contact reference person relating to this letter:

Bente Blauenfeldt
Customer Service Coordinator

Unomedical A/S
Birkerød Kongevej 2
3460 Birkerød
DENMARK

Tlf: + 45 48 10 30 36
Fax: + 45 48 10 30 00
E-mail: bente.blauenfeldt@convatec.com

For questions relating to your orders or replacement products, please contact your local Unomedical representative.

RECALL CONFIRMATION FORM FOR END-USERS

Consignee of the device:

NAME:	ADDRESS:	QUANTITY:

The following device(s) have been forwarded to you:

REF:	DEVICE:	LOT No:	QUANTITY:

The recipient confirms (please, tick off as applicable):

that none of the devices mentioned above are in my possession.

that some of the devices mentioned above remain in my possession.
They will be returned as per the instructions given by the distributor.

Number/ Lot(s) to be returned: _____ pieces

NAME (CAPITAL LETTERS) AND POSITION

SIGNATURE

DATE

ADDRESS

This form has been submitted by a representative of the distributor:

NAME

SIGNATURE

DATE

Description	Model Number	LOT Number
LEG BAG 350ML SHORT TUBE	08 613 1S-UMUK	303576 318057 328180 343448 349025
LEG BAG 350ML LONG TUBE	08 620 1S-UMUK	336878 360759
LEG BAG 500ML SHORT TUBE	12 612 1S-UMUK	303590 304855 310461 315604 308436 312682 314217 318060 324440 327168 330136 332021 331987 333125 338496 343461 336811 340605 344278 349027 349016 344279 355112 360426 350917 363564
	12 613 1S-UMUK	303591 307892 307891 304856 310462 315601 308437 314218 322469 318061 324441 325923 328185 332019 330138 330137 331985 332020 336895 344282 349020 349028 355115 344281 360430 350918
	12 618 1S-UMUK	308145 315598 308438 310463 314219 318062 328186
	12 629 1S-UMUK	303593 304859 308442 310466 315600 314223 324445 324444 326658 326657 326659 326660 334982 337856 337857 337858 349032 344274 360428 350921

LEG BAG 500ML LONG TUBE	12 620 1S-UMUK	303530 307893 304857 303592 315606 310464 308439 314220 312336 318063 324442 328187 331986 342270 345788 352773 349029 344280 355113 360689 360431
	12 621 1S-UMUK	307894 307895 308440 315602 310465 322470 314221 318064 324443 328188 325924 330140 330139 330141 332018 332017 331990 336335 336812 342271 344277 349017 344276 349026 355114 360427
	12 623 1S-UMUK	304858 315599 308441 314222 318065 328189 332212 342451 349018 344289 349031
	12 632 1S-UMUK	301607 301606 301605 308048 315595 314000 318066 324447 328191 328190 330142 330143 332211 336896 336897 342450 344275 349019 349030 360429 350922

LEG BAG 750ML SHORT TUBE	24 610 1S-UMUK	304860 308469 314225 328196 332015 331988 344286 350926
	24 612 1S-UMUK	308146 303615 308385 310483 312700 314226 318077 328198 328197 332013 331991 333194 336928 349021 344283 360432 360966
LEG BAG 750ML LONG TUBE	24 620 1S-UMUK	307917 312337 310484 314227 324478 318078 328199 332014 331989 336929 344287 343499 349023 344284 360433
	24 621 1S-UMUK	301603 303537 301602 301604 315603 314228 318079 324479 331992 330155 331393 331394 344288 331395 349024 349022 344285 360434

E4 2L NIGHT BAG WITH NRV	38 126 1S-UMUK	302070 306671 308474 312806 315596 324481 328201 330338 332444 335013 338927 342848 342847 342849 351085
	38 127 1S-UMUK	303538 144738 306672 142783 144739 312136 315597 314998 317986 317984 317985 317987 320090 320091 322764 322763 344960 346243 343507 347160 351081 344421 360345
	38 132 1S-UMUK	302071 306674 308475 312807 314999 315607 318564 322490 324482 327182 327183 327184 339105 343508 346245 351086 355649 344422 360347
	38 133 1S-UMUK	303535 304713 306675 307928 308476 312808 315000 315605 318565 324483 327174 327176 327175 339106 331993 327177 343281 343509 346244 350594 351088 361354 360346

A4 UM FF 117CM NFK	38 155 0 -10	303225 310316 320460 327277
UNOMEDICAL A4 CLOSED	38 155 1S-10	302929 137447 147475 137314 312813 312716 312811 312812 315190 315002 318189 318634 318567 318566 321313 321755 322988 324484 324606 326741 328204 329418 330299 336187 335203 332447 340913 338446 336340 333765 333234 339107 343510 340546 344198 346249 346250 350299 347662 352772 352548 357402 355653 357408 360967 358433 304284 303054 303055 306678 307735 310317 316017 312416 311877 311101 322962 319944 320664 321314 316628 322515 321756 322775 316803 324486 323479 323480 324485 325912 326568 328633 325940 328939 326019 326020 332448 338281 340548 335201 342112 338282 344325 340547 343255 345040 346197 347017 348294 350216 347886 351745 352654 352771 354922 354921 357904 358434 356820 357372 358388 357903 359237 359306 358407 364200 362124 360386 360756 360385 364092

UNOMEDICAL A4 CLOSED NFK/IH	38 162 1S-20	304106 310318 310319 312417 320666 316629 320665 319727 322776 322908 324607 338447 333764 341022 343722 343511 343288 344200 348569 347817 346247 348570 350154 347888 351746 352446 357404 357374 357373 355879 358390 360757 362347
UM-6 111CM NFK DRK FF SNB	41 064 1S-PFM	305776 316632 328634 335388 340155 347759 351764
A6 LUKKET SYSTEMPOSE MED	41 065 1S-PFM	304575 306309 309720 311104 314798 317331 320671 322315 325100 328635 333242 337520 339989 335389 343260 344857 344203 346202 344856 347760 346982 346203 348549 350300 349826 352388 350854 352812 352986 355009 355895 357411 358613 359550 361342 359956 365612 362125

A6 UM. FF 111CM NFK DRK	41 149 1S-20	303226
		304111
		305122
		308751
		311649
		309721
		314259
		311880
		312631
		313187
315591		
316633		
319113		
318416		
317332		
320673		
319730		
320672		
322778		
322779		
324817		
323486		
323485		
324816		
324608		
324286		
324818		
326015		
325804		
325805		
328636		
328637		
326017		
326014		
330487		
334274		
326016		
336933		
335590		
333778		
332451		
334409		
334187		
340550		
338450		
336476		
336477		
336266		
333779		
340551		
340157		
340914		
344423		
340017		
341872		
340156		
339168		
340423		
344326		
343515		
343516		
347352		
354544		
353706		
355899		
357375		
356822		
356716		
359307		
359551		
357412		
360978		
360882		
360881		
	41 149 1S-30	365334 361782
	41 149 1S-40	342639 360600
A4 UM PRECO.CAT.LAT.IH	43 924 1S-20 43 926 1S-20 43 928 1S-20	321794 321795 321796
A6 UM. PRECON.CAT.SIL	44 924 1S-20	321797 347921 357409
	44 926 1S-20	321798 347922 352410 357410
	44 928 1S-20	321799 349403 352411

4 L BLADDER WASH BAG BO (FFV)		316885
5 L BLADDER WASH BAG BO (FFV)		316886
6 L BLADDER WASH BAG BO (FFV)		312866
7 L BLADDER WASH BAG BO (FFV)		319115
8 L BLADDER WASH BAG BO (FFV)		315005
9 L BLADDER WASH BAG BO (FFV)		321317
10 L BLADDER WASH BAG BO (FFV)		322493
11 L BLADDER WASH BAG BO (FFV)		322777
12 L BLADDER WASH BAG BO (FFV)		324609
13 L BLADDER WASH BAG BO (FFV)		326744
14 L BLADDER WASH BAG BO (FFV)		326981
15 L BLADDER WASH BAG BO (FFV)		330157
16 L BLADDER WASH BAG BO (FFV)		337711
17 L BLADDER WASH BAG BO (FFV)		332453
18 L BLADDER WASH BAG BO (FFV)		332946
19 L BLADDER WASH BAG BO (FFV)		336720
20 L BLADDER WASH BAG BO (FFV)		338928
21 L BLADDER WASH BAG BO (FFV)		340552
22 L BLADDER WASH BAG BO (FFV)	48 110 1S-20	342113
23 L BLADDER WASH BAG BO (FFV)		340916
24 L BLADDER WASH BAG BO (FFV)		344327
25 L BLADDER WASH BAG BO (FFV)		346422
26 L BLADDER WASH BAG BO (FFV)		348583
27 L BLADDER WASH BAG BO (FFV)		346984
28 L BLADDER WASH BAG BO (FFV)		350156
29 L BLADDER WASH BAG BO (FFV)		350855
30 L BLADDER WASH BAG BO (FFV)		350853
31 L BLADDER WASH BAG BO (FFV)		350787
32 L BLADDER WASH BAG BO (FFV)		352549
33 L BLADDER WASH BAG BO (FFV)		352655
34 L BLADDER WASH BAG BO (FFV)		355893
35 L BLADDER WASH BAG BO (FFV)		358387
36 L BLADDER WASH BAG BO (FFV)		359686
37 L BLADDER WASH BAG BO (FFV)		359309
38 L BLADDER WASH BAG BO (FFV)		361747
39 L BLADDER WASH BAG BO (FFV)		360885
40 L BLADDER WASH BAG BO (FFV)		360884
41 L BLADDER WASH BAG BO (FFV)	48 110 1S-40	358386
4 L BLADDER WASH BAG WITH PUMP		308612
5 L BLADDER WASH BAG WITH PUMP		316887
6 L BLADDER WASH BAG WITH PUMP		330003
7 L BLADDER WASH BAG WITH PUMP		338511
8 L BLADDER WASH BAG WITH PUMP		339525
9 L BLADDER WASH BAG WITH PUMP	48 111 1S-10	342739
10 L BLADDER WASH BAG WITH PUMP		345042
11 L BLADDER WASH BAG WITH PUMP		344208
12 L BLADDER WASH BAG WITH PUMP		352550
13 L BLADDER WASH BAG WITH PUMP		355894
14 L BLADDER WASH BAG WITH PUMP		362232