

SPIRE HD CATHETER RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT

- 1) Decathlon 24CM DECATHLON STD KIT Models: DE19SH24 and DE19SH24-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Recall # Z-0288-2010;
- 2) 28CM DECATHLON STD KIT Models: DE23SH28 and DE23SH28-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Recall # Z-0289-2010;
- 3) 32CM DECATHLON STD KIT Model: DE27SH32 and DE27SH32-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Recall # Z-0290-2010;
- 4) 36CM DECATHLON STD KIT Models: DE31SH36 and DE31SH36-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit 28cm Decathlon Std Kit. Recall # Z-0291-2010;
- 5) 40CM DECATHLON STD KIT Models: DE35SH40 and DE35SH40-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Recall # Z-0292-2010;
- 6) 55CM DECATHLON STD KIT Models: DE50SH55 and DE50SH55-K 15.5 Fr Polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Recall # Z-0293-2010;
- 7) 24CM DECATHLON FUNNEL TIP STD KIT Model: DF19SH24 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0294-2010;
- 8) 28CM DECATHLON FUNNEL TIP STD KIT Model: DF23SH28 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0295-2010;
- 9) 32CM DECATHLON FUNNEL TIP STD KIT Model: DF27SH32 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away

sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0296-2010;

10) 36CM DECATHLON FUNNEL TIP STD KIT Model: DF31SH36 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free Recall # Z-0297-2010;

11) 40CM DECATHLON FUNNEL TIP STD KIT Model: DF35SH40 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0298-2010;

12) 55CM DECATHLON FUNNEL TIP STD KIT Model: DF50SH55 DECATHLON FUNNEL TIP 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0299-2010;

13) 24CM DECATHLON FUNNEL TIP CATHETER Model: DF19SH24-100 DECATHLON FUNNEL TIP - CATHETER ONLY 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # Z-0300-2010;

14) 28CM DECATHLON FUNNEL TIP CATHETER Model: DF23SH28-100 DECATHLON FUNNEL TIP - CATHETER ONLY 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # -0301-2010;

15) 32CM DECATHLON FUNNEL TIP CATHETER Model: DF27SH32-100 DECATHLON FUNNEL TIP - CATHETER ONLY 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # Z-0302-2010;

16) 24CM DECATHLON MINI KIT Model: DM19SH24 DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 16 Fr valved peel-away sheath dilator, tunneling stylet, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0303-2010;

17) 28CM DECATHLON MINI KIT Model : DM23SH28 DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 16 Fr valved peel-away sheath dilator, tunneling stylet, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0304-2010;

18) 32CM DECATHLON MINI KIT Model: DM27SH32 DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge intro. Recall # Z-0305-2010;

19) 24CM DECATHLON EXCHANGE KIT Model: DX19SH24-XP DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 16 Fr valved peel-away sheath dilator, tunneling stylet, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0306-2010;

20) 28CM DECATHLON EXCHANGE KIT Model: DX23SH28-XP DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 16 Fr valved peel-away sheath dilator, tunneling stylet, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0307-2010;

21) 32CM DECATHLON EXCHANGE KIT Model: DX27SH32-XP DECATHLON MINI KIT 15.5 Fr polyurethane twin lumen hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 16 Fr valved peel-away sheath dilator, tunneling stylet, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0308-2010;

22) 24CM DECATHLON GOLD STD KIT Models: DEC19SH24 and DEC19SH24-K DECATHLON GOLD 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0309-2010;

23). 28CM DECATHLON GOLD STD KIT Model: DEC23SH28 and DEC23SH28-K. Recall # Z-0310-2010;

24) 32CM DECATHLON GOLD STD KIT Models: DEC27SH32 and DEC27SH32-K DECATHLON GOLD 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0311-2010;

25) 36CM DECATHLON GOLD STD KIT Model: DEC31SH36 and DEC31SH36-K
DECATHLON GOLD 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0312-2010;

26) 40CM DECATHLON GOLD STD KIT Model: DEC35SH40 and DEC35SH40-K
DECATHLON GOLD 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0313-2010;

27) 55CM DECATHLON GOLD STD KIT Models: DEC50SH55 and DEC50SH55-K
DECATHLON GOLD 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0314-2010;

28) 24CM DECATHLON GOLD FUNNEL TIP STD KIT Models: DFC19SH24 and DFC19SH24-K
DECATHLON GOLD FUNNEL TIP 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0315-2010;

29) 28CM DECATHLON GOLD FUNNEL TIP STD KIT Models: DFC23SH28 and DFC23SH28-K
DECATHLON GOLD FUNNEL TIP 15.5 Fr polyurethane twin lumen Heparin coated hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0316-2010;

30) 32CM DECATHLON GOLD FUNNEL TIP STD KIT Model: DFC27SH32 15.5 Fr
polyurethane twin lumen Heparin coated hemodialysis catheter with separated funnel tips, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter with stylet, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch guidewire, 12Fr dilator, 14Fr dilator, 16Fr peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0317-2010;

31) 24CM ALTA LR STANDARD KIT High Flow Recirculation Catheter Model: AL19SH24
ALTA CATHETER WITH SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis

catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0318-2010;

32) 28CM ALTA LR STANDARD KIT High Flow Recirculation Model: AL23SH28 ALTA CATHETER WITH SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0319-2010;

33) 32CM ALTA LR STANDARD KIT Model: AL27SH32 ALTA CATHETER WITH SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0320-2010;

34) 36CM ALTA LR STANDARD KIT Model: AL31SH36 ALTA CATHETER WITH SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0321-2010;

35) 40CM ALTA LR STANDARD KIT Model: AL35SH40 ALTA CATHETER WITH SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0322-2010;

36) 24CM ALTA LR STANDARD KIT Model: AL19NH24 ALTA CATHETER WITH NO SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff, and no side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0323-2010;

37) 28CM ALTA LR STANDARD KIT Model: AL23NH28 ALTA CATHETER WITH NO SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff, and no side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0324-2010;

38) 32CM ALTA LR STANDARD KIT Model: AL27NH32 ALTA CATHETER WITH NO SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff, and no side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0325-2010;

39) 36CM ALTA LR STANDARD KIT Model: AL31NH36 ALTA CATHETER WITH NO SIDE HOLES 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff, and no side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0326-2010;

40) 24CM ALTA EXCHANGE KIT Model: AL19SH24-XP ALTA EXCHANGE KIT 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # Z-0327-2010;

41) 28CM ALTA EXCHANGE KIT Model: AL23SH28XP ALTA EXCHANGE KIT 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # Z-0328-2010;

42) 32CM ALTA EXCHANGE Model: AL27SH32XP ALTA EXCHANGE KIT 15.5 Fr polyurethane twin lumen fixed tip hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Latex free. Recall # Z-0329-2010;

43) 24CM ALTA LR GOLD STD KIT Model: ALC19SH24 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0330-2010;

44) 28CM ALTA LR GOLD STD KIT Model: ALC23SH28 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0331-2010;

45) 32CM ALTA LR GOLD STD KIT Model: ALC27SH32 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0332-2010;

46) 36CM ALTA LR GOLD STD KIT Model: ALC31SH36 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0333-2010;

47) 40CM ALTA LR GOLD STD KIT Model: ALC35SH40 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0334-2010;

48) 55CM ALTA LR GOLD STD KIT Model: ALC50SH55 ALTA GOLD 15.5 Fr polyurethane twin lumen fixed tip heparin coated hemodialysis catheter, cuff and side holes for chronic hemodialysis and apheresis. Kit contains catheter, 18 gauge introducer needle, 12cc syringe, J/straight 0.038 inch x 100 cm marked guidewire, 12Fr dilator, 14Fr dilator, 16Fr valved peel-away sheath/dilator, #11 scalpel, tunneling stylet, (4) gauze sponges, wound dressing, (2) injection sealing caps, and warning label. Latex free. Recall # Z-0335-2010

CODE: All lot codes

RECALLING FIRM/MANUFACTURER: Spire Biomedical, Inc., Bedford, MA, by letter dated October 22, 2009. Firm initiated recall is ongoing.

REASON: There is a possibility that the catheter tubing could separate from the hub/bifurcation of the device. If this occurs, bleeding is the primary clinical complication likely to result from catheter tubing/hub separation. A second potential clinical complication is air embolism, particularly for the segment of the patient population that develops negative central venous pressure during normal respiration.

VOLUME OF PRODUCT IN COMMERCE: 55,218 units

DISTRIBUTION