

Smith & Nephew Orthopaedics GmbH • Postfach 64 • 78501 Tuttlingen

Name and address of hospital

June 02, 2009

Notification of a product recall

Internal case number: R090012
 Item description: DYONICS 25 Tube Sets

Item Number	Item Description	Lot Number
7211005	DYONICS 25 Fluid Management System Disposable Inflow/Outflow Tubeset With Single Suction	0149J, 0149H, 0149K, 0769P, 0799N, 0899K, 0919K, 09609W, 11009K, 12709T, 12809M, 12809N, 13509H, 1688L, 1788H, 1798F, 1918F, 1928H, 1928HR, 1998X, 2218H, 2258F, 2278F, 2328H, 2388J, 2398F, 2418T, 2478K, 2758U, 2758Y, 2758Y, 2778F, 2778FR, 2898F, 2908X, 2908Y, 3048N, 3098F, 3258U, 3258V, 3468U, 3468V
7211006	DYONICS 25 Fluid Management System Disposable Inflow/Outflow Tubeset With Forked Suction	0169H, 0299J, 0409K, 0409L, 0409M, 0479U, 0479X, 0489F, 0489H, 0859F, 0899J, 0919F, 12609V, 12709K, 1618F, 1618L, 1618LR, 1628F, 1628FR, 1648K, 1648KR, 1758J, 1838K, 1908M, 1938F, 2058L, 2528F, 2528FR, 2558F, 2698J, 2748F, 2748P, 2808U, 2838L, 2848H, 2878N, 2908U, 2908V, 3038N, 3048M, 3258P

Dear Sir or Madam,

The company has become aware that certain DYONICS 25 tubeset kits identified in the table above may not meet the high quality standards of Smith & Nephew which could result in a potential compromise of the sterile barrier.

With this action we want to avoid any possible risk. Therefore we are recalling the affected products.



According to our traceability records you received the items listed in the table below:

Affected item number	Affected lot number	Quantity	Delivery date

Please send the affected items to the following address or give them to our sales representative, which will contact you promptly.

The address of the correspondent Smith & Nephew subsidiary

Please apologize any inconveniences this matter may have caused you.

If you should have any query, please do not hesitate to contact our Regulatory Affairs & Quality Manager Mr. Brunnen (0049 (0) 7461 208 144).

Best regards

Smith & Nephew GmbH



Regulatory Affairs

Mailing List:

Correspondent sales representative