

Urgent: Field Safety Notice

Model 8637-20 (20ml) SynchroMed II Implantable Infusion Pumps
Mis-packaged as Model 8637-40 (40ml) Pumps

Recall

September 2010

Medtronic ref: FA488

Dear Healthcare Professional:

Medtronic is retrieving a small number of Model 8637-40 Implantable Infusion Pumps that were packaged with the incorrect model pump. Affected product contains a Model 8637-20 SynchroMed II implantable infusion pump rather than the Model 8637-40 SynchroMed II implantable infusion pump.

The following SynchroMed II Model 8637-40 pump serial numbers are being retrieved by Medtronic.

NGP344795H	NGP344980H	NGP345265H	NGP346472H	NGP346630H
NGP344860H	NGP344994H	NGP345277H	NGP346502H	
NGP344874H	NGP345211H	NGP345298H	NGP346610H	
NGP344978H	NGP345250H	NGP345302H	NGP346619H	

Please note that this is only an issue with product labeling / packaging. The Model 8637-20 pumps that were included in the Model 8637-40 product packaging meet product specifications and function properly. The only difference between the Model 8637-40 and 8637-20 pumps is the drug reservoir size. The only potential hazard is defined as revision surgery to replace an incorrect model pump.

Model	Reservoir Size
8637-40	40 ml
8637-20	20 ml

The Model number and serial number are engraved on the front of the pump.



The Competent Authority of your country has been notified of this action. This notice needs to be passed to all those who need to be aware within your organization.

We appreciate your assistance with this matter and regret any inconvenience this may have cause you or your patients. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients. If you have any questions or comments, please contact your Medtronic representative at [<insert contact info>](#)

Sincerely,

Country Manager