

**Appendix**

Attention: Nurse in Charge

Neonatal Intensive Care Unit

February 2012

**URGENT Product information notice**

**Neonatal Endotracheal Tube Clamps SCP clamps**

In our notice October 2011 we reported that some customers experienced issues in the use of the clamps due to the change in the materials used in the manufacture of the SCP clamp and the Portex Endotracheal tubes (ET), due to legislative requirements.

Issues reported were possible slippage between the clamp and the ET tube. An interim modification was made to the clamp. This interim change meant that it was possible to over tighten and partially occlude the ET tube. Our SCP clamp have now been further modified and tested with a new material.

As a precaution we offer to exchange Capatex medical product prior to batch 1002854.

Further to our notice sent out in October 2011, we wish to inform all users that all current production and stock are now made from the new design and new material.

Please, however, note if you are using old or new stock it is imperative that the correct diameter clamp is selected and checks must be made to ensure that the ET tube is not slipping or being compressed. As per our instructions for use and the note on the product packaging, if a Vygon tube is used select a size larger clamp.

Product Code	Description		NSV Code	Use Portex	Use Vygon
CM-SCP20-ENDO	Neonatal Endotracheal Tube Holder	2.0mm	FTH073	2.0 tube	
CM-SCP25-ENDO	Neonatal Endotracheal Tube Holder	2.5mm	FTH074	2.5 tube	2.0 tube
CM-SCP30-ENDO	Neonatal Endotracheal Tube Holder	3.0mm	FTH075	3.0 tube	2.5 tube
CM-SCP35-ENDO	Neonatal Endotracheal Tube Holder	3.5mm	FTH076	3.5 tube	3.0 tube
CM-SCP40-ENDO	Neonatal Endotracheal Tube Holder	4.0mm	FTH077	4.0 tube	3.5 tube

If you require any further information please contact our customer services team on 0115 978 6111

Yours sincerely

Gabriel Straus

Managing Director

**Please Fax this sheet back to Capatex to acknowledge receipt and understanding to the following number. 01159 786222**

Hospital		Name		Position	
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Attention: Nurse in Charge  
 Neonatal Intensive Care Unit  
 October 2011

**URGENT Product information notice**

**Neonatal Endotracheal Tube Clamps**

**SCP clamps**

The SCP clamp is now manufactured from a DEHP free material as required by recent changes in regulation. The change in material may result in a potential slippage between the SCP clamp and the Portex ET tube who's material has also changed . The clamp has been modified and it has been reported that the modification has resulted in a possible compression of the ET tube when the clamp is over tightened, which could cause obstruction when a suction catheter is passed through.

**Recommendation**

We are working with a new material to resolve the issue and make the clamp more tactile against the ET tube. In the interim, our recommendation is to test the clamp on the penultimate notch to check that the tube does not move in situ

Product Code	Description		NSVCode
CM-SCP20-ENDO	Neonatal Endotracheal Tube Holder	2.0mm	FTH073
CM-SCP25-ENDO	Neonatal Endotracheal Tube Holder	2.5mm	FTH074
CM-SCP30-ENDO	Neonatal Endotracheal Tube Holder	3.0mm	FTH075
CM-SCP35-ENDO	Neonatal Endotracheal Tube Holder	3.5mm	FTH076
CM-SCP40-ENDO	Neonatal Endotracheal Tube Holder	4.0mm	FTH077

All of the above are supplied in boxes of 20

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Yours Sincerely

Gabriel Strauss  
 Managing Director