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الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٣٧/٢٥  
رقم الصادر: ١٣٧٧/١٤٨  
بيروت، في: ٢٨ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس. Staples and staple guns.

الجهاز المعنى بالمتابعة:

- Staples and staple guns; circular/intraluminal stapler, Proximate HCS.  
Trade Mark: Ethicon Endo Surgery Inc.  
Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

✓ دائرة البرامج والمشاريع

- المحفوظات

مدير عام الصحة



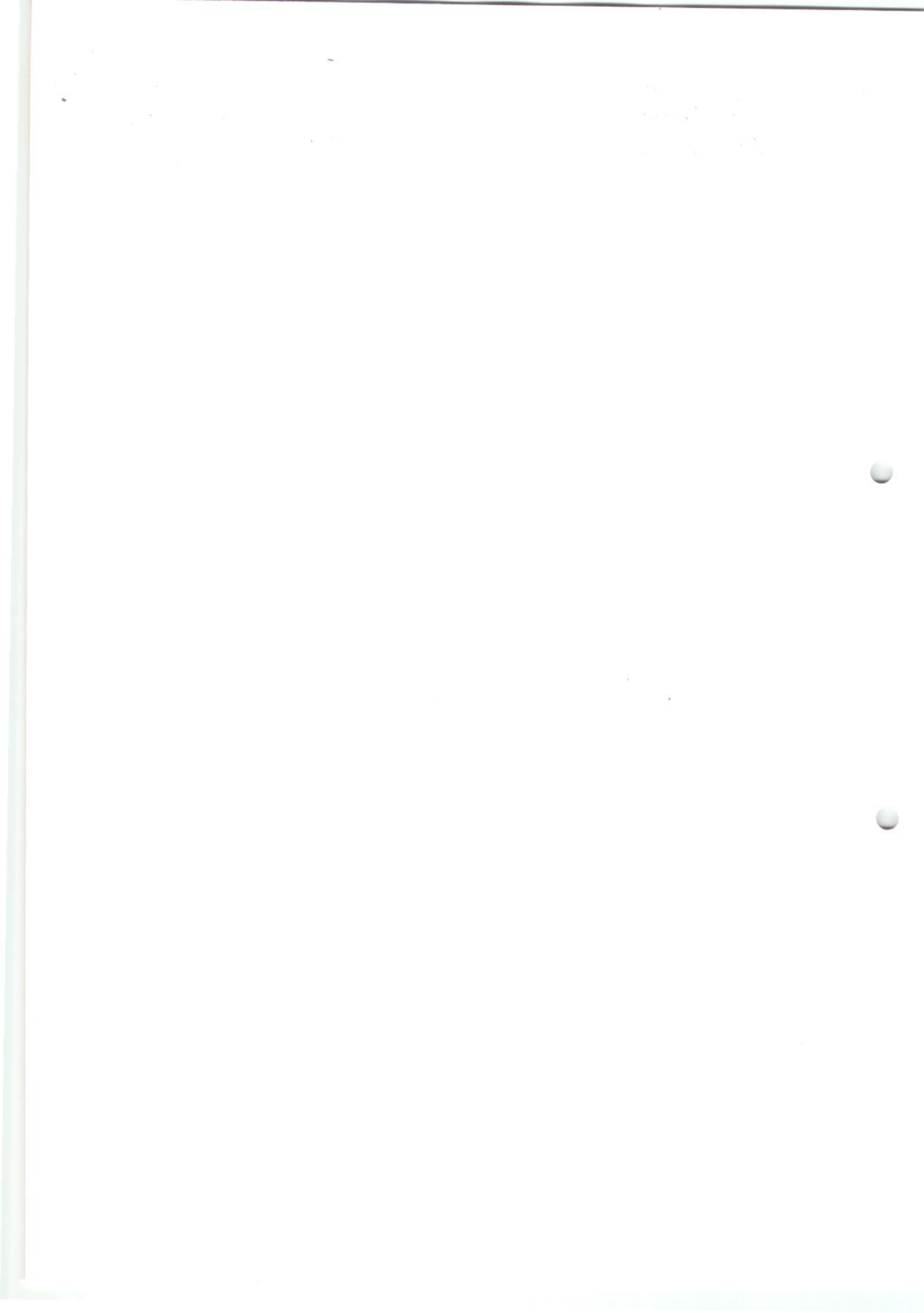
وثيقة مصابقة للأصناف

بيروت في ٢٠ آب ٢٠١٢

رئيس قسم أمانة السر

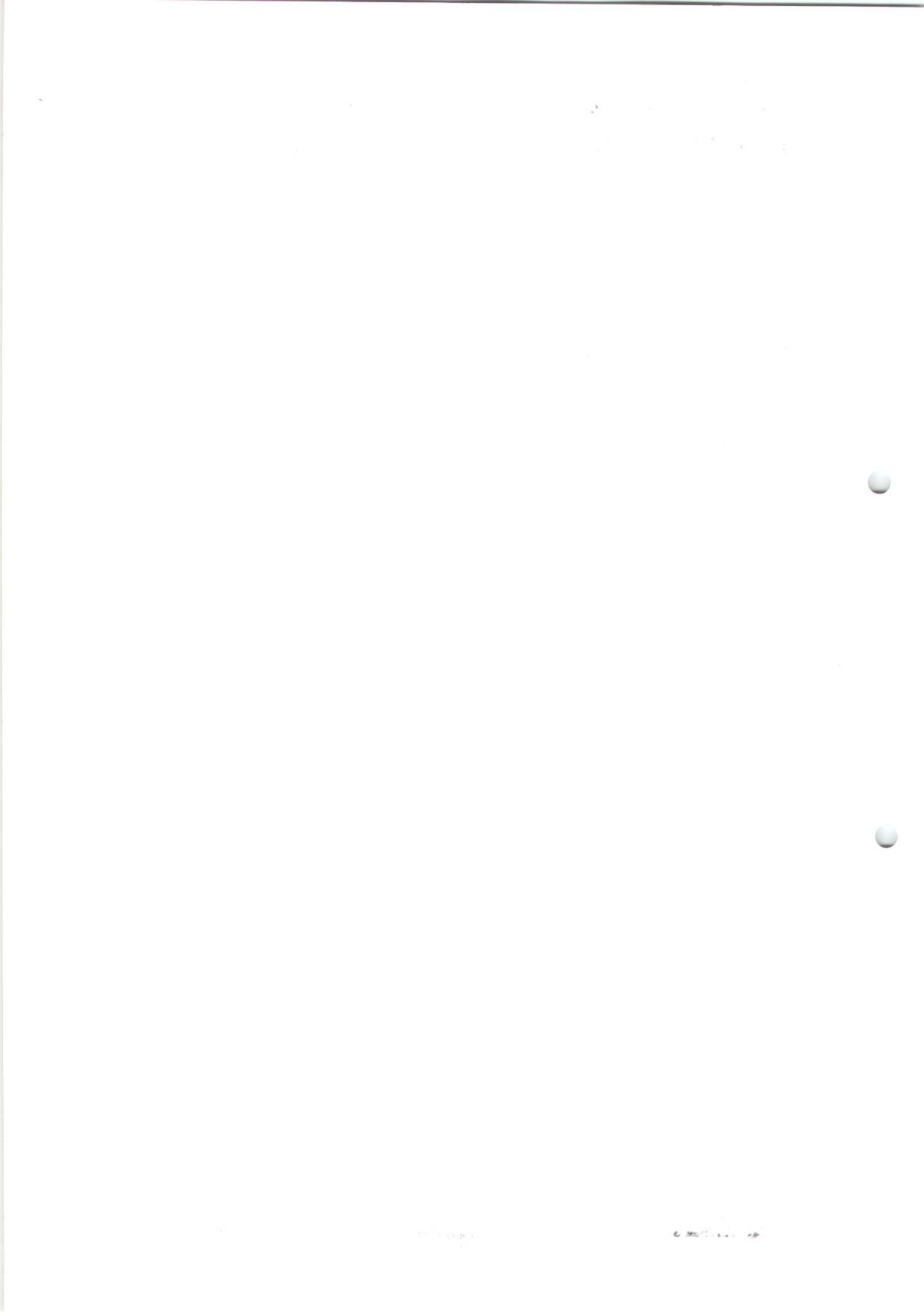
عناية غصن





# URGENT FIELD SAFETY NOTICE

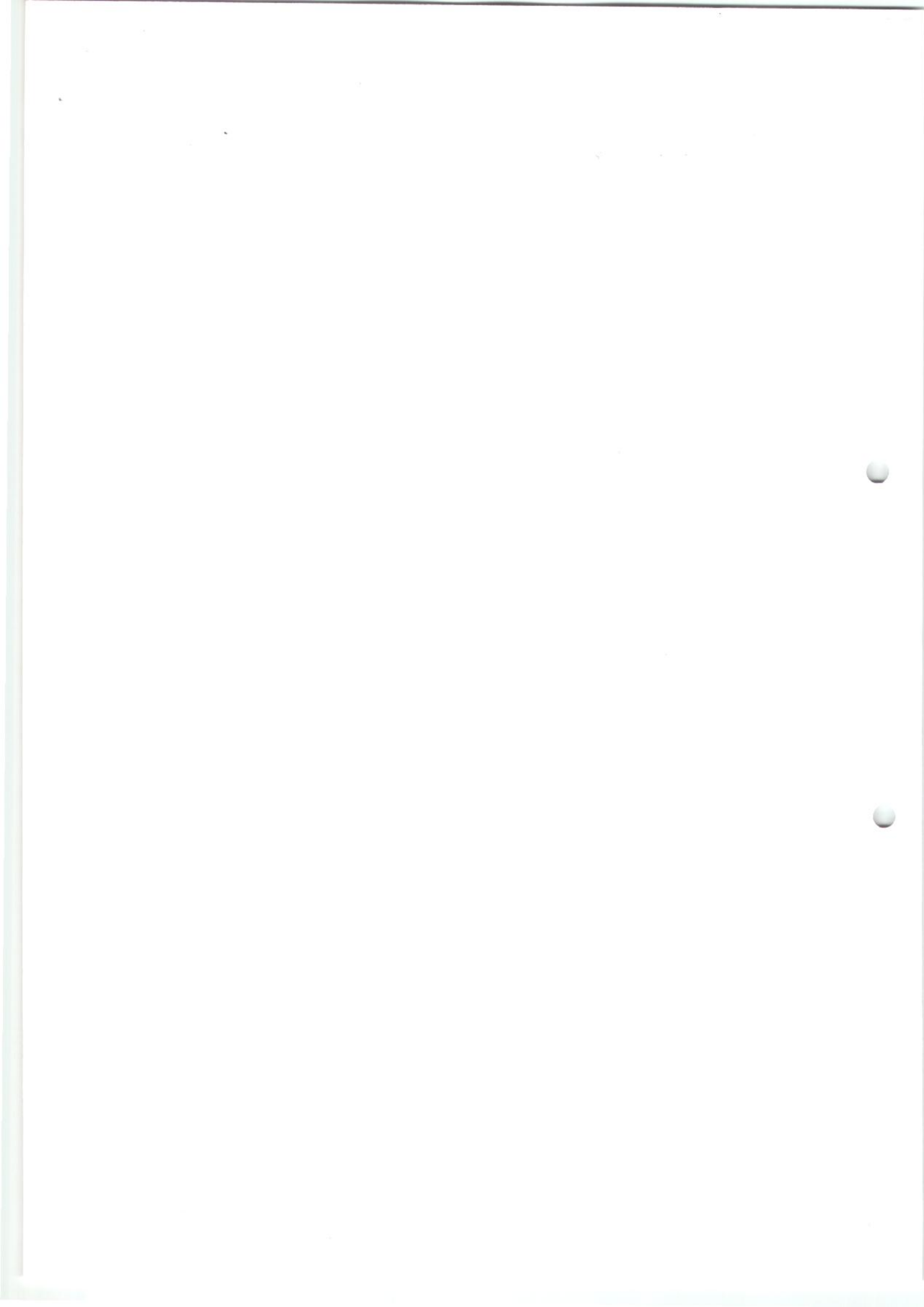
ATTENTION	Customer - Operating Room Director and Materials Management				
TYPE OF ACTION	URGENT DEVICE RECALL				
REF / DATE	PPH-2012-08 / 02-August-2012				
PRODUCT	Ethicon Endo-Surgery has initiated a voluntary global recall for specific production lots of <ul style="list-style-type: none"> <li>• PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set Product Code: PPH03</li> <li>• PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set Product Code: PPH01</li> </ul>				
DEVICE DETAILS	The recall involves the following product codes and lot numbers identified in Attachment A <table border="1" data-bbox="489 633 1378 754"> <tr> <td>PPH03</td> <td>PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set</td> </tr> <tr> <td>PPH01</td> <td>PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set</td> </tr> </table> <p>See Attachment A for detailed descriptions of the affected lot numbers. See Attachment B for images to help identify affected products.</p>	PPH03	PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set	PPH01	PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set
PPH03	PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set				
PPH01	PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set				
REASON	Ethicon Endo-Surgery has initiated a voluntary global recall for specific production lots of <ul style="list-style-type: none"> <li>• PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set Product Code: PPH03</li> <li>• PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set Product Code: PPH01</li> </ul> <p>due to difficulty firing the device which may result in incomplete firing stroke that may result in an incomplete staple formation. We are working to implement actions to resume production.</p>				
ACTION	We need your help in ensuring that <b>all affected products</b> are located, accounted for, and returned to <b>[Affiliate Name]</b> .  <b>EFFECTIVE IMMEDIATELY – DO NOT USE THIS PRODUCT</b> <ol style="list-style-type: none"> <li>1) Examine your inventory immediately to determine if you have affected product on hand and <b>remove</b> the affected product.</li> <li>2) Fill out the Business Reply Form and return it back to <b>[Affiliate Name]</b> within 3 business days, <b>even if you do not have affected product</b>. If you have product to be returned, keep a copy of this form for your records.</li> <li>3) To return affected product, enclose a copy of the Business Reply Form with the product, and use the pre-paid shipping label to return to:  <b>[Affiliate Name / Affiliate Address]</b></li> </ol> <p><b>Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help.</b></p>				
TRANSMISSION	Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.				





## URGENT FIELD SAFETY NOTICE

<b>CONTACT</b>	<p>Ethicon Endo-Surgery is dedicated to ensuring we implement this voluntary global recall as quickly and effectively as possible.</p> <p>[Affiliate Name] will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form.</p> <p>If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name].</p> <p>We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible.</p>
<b>CONFIRMATION</b>	<p>This action has been notified to the appropriate Regulatory Agencies.</p>





**Ethicon  
Endo-Surgery**

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Attachment A

REF: PPH-2012-08

**ATTACHMENT A**

**Product Codes and Lot Number List**

<b>Product Code:</b>									
PPH03-PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set									
<b>Lot Numbers:</b>									
H43M2G	H43W3A	H4439R	H4485W	H44F1D	H44T39	J4A42J	J4AC67	J4AK0U	J4AV0L
H43M3T	H43W3N	H44409	H4494E	H44F1M	H44T3C	J4A47E	J4AC6H	J4AK2D	J4AW0R
H43M80	H43W4K	H4440K	H4494J	H44F60	H44T45	J4A47F	J4AD0D	J4AK3H	J4AW0T
H43M8V	H43W4Z	H4440L	H44952	H44F61	H44T46	J4A50D	J4AD0E	J4AK4U	J4AW5P
H43M8Z	H43X76	H4441G	H4495W	H44F79	H44U1A	J4A51E	J4AD0J	J4AK53	J4AW5R
H43M9G	H43X77	H4444R	H4495X	H44F7L	H44U3M	J4A52R	J4AD52	J4AK58	J4AX0F
H43N0E	H43X8P	H44451	H44970	H44F85	H44U59	J4A532	J4AD5V	J4AK87	J4AX16
H43N0L	H43X8Z	H44458	H44976	H44F86	H44U5Z	J4A583	J4AD9F	J4AK8N	J4AX1P
H43N0M	H43Y03	H4445M	H4497G	H44F8Y	H44U67	J4A598	J4AE03	J4AK9P	J4AX36
H43N1A	H43Y0F	H4445N	H4497N	H44F9E	H44V04	J4A59M	J4AE0F	J4AL1L	J4AX3K
H43N1C	H43Y13	H4446U	H4497Y	H44F9L	H44V0D	J4A59N	J4AE0X	J4AL2F	J4AX48
H43N28	H43Y58	H4447G	H44A1P	H44F9W	H44V5W	J4A645	J4AE4R	J4AL4F	J4AX5T
H43N3H	H43Y5K	H44485	H44A4G	H44G58	H44V64	J4A666	J4AE51	J4AL58	J4AX6Y
H43P0N	H43Y88	H44486	H44A59	H44G9G	H44V65	J4A67A	J4AE5F	J4AL68	J4AX7E
H43P1E	H43Y8M	H44493	H44A5A	H44G9H	H44V6Y	J4A67J	J4AE8C	J4AL8F	J4AX8G
H43P2Z	H43Y8Z	H4452M	H44A63	H44G9K	H44V6Z	J4A688	J4AF4M	J4AL9A	J4AX8H
H43P3F	H43Y9N	H44534	H44A69	H44H06	H44V93	J4A76M	J4AF51	J4AL9C	J4AY2D
H43P52	H43Y9Z	H4453K	H44A6A	H44H3V	H44V94	J4A77U	J4AF7X	J4AM0V	J4AY40
H43P5P	H43Z0G	H4453W	H44A73	H44H3W	H44W69	J4A78J	J4AF89	J4AM0W	J4AY41
H43P6K	H43Z0X	H4454H	H44A86	H44J3X	H44W8F	J4A78U	J4AF8R	J4AM1G	J4AY9A
H43P78	H43Z20	H4454M	H44A87	H44J4F	H44X14	J4A810	J4AF9V	J4AM2D	J4AZ06
H43P7E	H43Z21	H4462F	H44A98	H44K1U	H44X6K	J4A81M	J4AG07	J4AM8M	J4AZ0E
H43R4P	H43Z2K	H4462G	H44A99	H44K24	H44X7Z	J4A81N	J4AG3T	J4AM8N	J4AZ0Z
H43R7J	H43Z2Y	H4465R	H44C02	H44K7P	H44Y4F	J4A82N	J4AG3U	J4AM8P	J4AZ15
H43T47	H43Z3Y	H4465T	H44C0C	H44K8V	H44Y5L	J4A830	J4AG45	J4AN0D	J4AZ2G
H43T4T	H44069	H4466U	H44C0K	H44L0C	H44Y6A	J4A856	J4AG4T	J4AN9Y	J4AZ2Z
H43T50	H4407K	H4468G	H44C0Y	H44L25	H44Y6R	J4A85J	J4AG9H	J4AN9Z	J4AZ35
H43T5Z	H4407L	H4468N	H44C3K	H44L7D	H44Y6T	J4A86A	J4AG9L	J4AP0L	J4AZ3A
H43U0F	H4409A	H44693	H44C3X	H44L8V	H44Y8H	J4A86L	J4AG9U	J4AP4F	J4AZ3J
H43U0X	H44190	H4469A	H44C4R	H44M0M	H44Z4F	J4A86M	J4AH0L	J4AP5X	J4AZ3Z
H43U15	H4424X	H4469V	H44C4T	H44M7K	J4A01M	J4A87G	J4AH1E	J4AP6D	J4AZ5G
H43U1U	H44251	H44706	H44C68	H44M7L	J4A06C	J4A94N	J4AH29	J4AP6X	J4AZ5U
H43U25	H4426A	H4470V	H44C7W	H44N3Y	J4A071	J4A94P	J4AH2H	J4AR2R	J4AZ83
H43U2D	H4427Y	H4470W	H44C9T	H44N6C	J4A078	J4A97A	J4AH2T	J4AR5R	J4C03P



**Ethicon  
Endo-Surgery**

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**Attachment A**

**REF: PPH-2012-08**

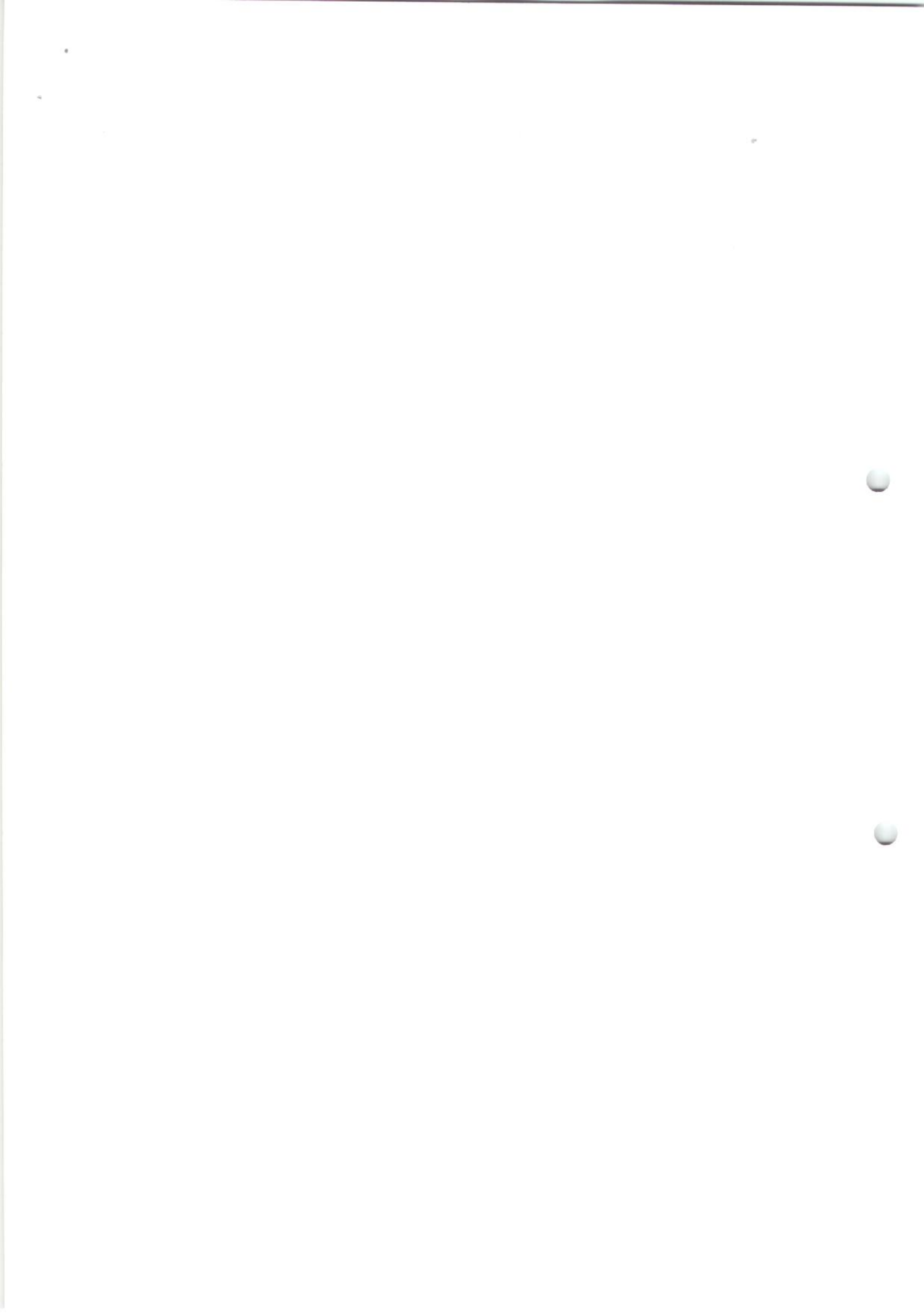
**Product Code:**

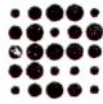
**PPH03-PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set**

**Lot Numbers:**

H43U2F	H44290	H4475Z	H44C9U	H44N6D	J4A10C	J4A98Y	J4AH2U	J4AR5T	J4C03R
H43U30	H4433X	H4476F	H44E24	H44N6G	J4A10K	J4AA0F	J4AH3K	J4AR7X	J4C04L
H43U63	H4434E	H4476W	H44E25	H44P26	J4A10L	J4AA0G	J4AH4R	J4AR7Y	J4C05T
H43U7N	H44351	H44784	H44E7E	H44P2H	J4A117	J4AA24	J4AH4Z	J4AR81	J4C05U
H43U7Z	H44352	H4478T	H44E7P	H44P2J	J4A118	J4AA2F	J4AJ18	J4AT35	J4C063
H43U93	H4435Z	H4478U	H44E80	H44P32	J4A29M	J4AA2P	J4AJ1H	J4AT36	J4C064
H43U99	H44360	H4479F	H44E81	H44P46	J4A29N	J4AA2U	J4AJ1K	J4AT50	J4C12V
H43V03	H4436T	H4479K	H44E8L	H44P4M	J4A29X	J4AA2Z	J4AJ29	J4AT51	
H43V0J	H44375	H4479W	H44E8M	H44P58	J4A35K	J4AA3U	J4AJ2N	J4AT6T	
H43V12	H4437H	H4480L	H44E8Y	H44P6N	J4A36H	J4AA86	J4AJ3D	J4AT6U	
H43V2Z	H4437Y	H44835	H44E8Z	H44P70	J4A36J	J4AA87	J4AJ3E	J4AT74	
H43V30	H4437Z	H44836	H44E9R	H44P71	J4A37R	J4AA8G	J4AJ4X	J4AU2N	
H43V3V	H4438T	H4483Z	H44F04	H44R0H	J4A38J	J4AA9J	J4AJ5J	J4AU2P	
H43W1R	H4438Y	H4484L	H44F0D	H44R3Z	J4A38K	J4AA9V	J4AJ6G	J4AU3G	
H43W22	H44391	H44855	H44F0T	H44R5V	J4A41M	J4AC0E	J4AJ9W	J4AU3H	
H43W2E	H4439E	H44859	H44F0U	H44T38	J4A41N	J4AC5Z	J4AK0T	J4AV0K	







**Ethicon  
Endo-Surgery**

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**Attachment A**

**REF: PPH-2012-08**

**Product Code:**

**PPH01 - PROXIMATE® HCS Procedure for Prolapse and Hemorrhoids (PPH) Set**

**Lot Numbers:**

H4487C	H44A2X	J4AE3L
H43R2F	H44C0Z	J4AE46
H43R2Z	H44F2N	J4AE9C
H43T79	H44G07	J4AF1C
H43X1M	H44G0D	J4AF3Y
H43X2C	H44H45	J4AG0E
H43Y1C	H44H46	J4AG6T
H43Y1E	H44J06	J4AJ6H
H43Y5G	H44J0M	J4AK6N
H43Y7C	H44M4P	J4AK72
H4413D	H44M8R	J4AM2V
H44152	H44N49	J4AN12
H4437D	H44W1H	J4AP15
H4437E	H44X5K	J4AP50
H4450E	H44Y7P	J4AT7W
H4461K	H44Y96	J4AV66
H4467D	H44Z09	J4AW6F
H44813	J4A42P	J4AY6K
H44886	J4A65H	J4AY9X
H44927	J4A679	J4AZ8A
H44988	J4A88H	J4C16X
H44989	J4AD14	J4C22E
H44A1R	J4AD15	

