ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

ATTENTION	**Operating Room Director and Materials Management**
TYPE OF ACTION	**URGENT DEVICE RECALL**
REF / DATE	ER320-2013-04 and ER320-2013-04PP / 26-April-2013
PRODUCT	Ethicon Endo-Surgery (Ethicon) is initiating a voluntary recall for LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers (ER320)
DEVICE DETAILS	The recall involves the following product codes:

Device Full Name	**Product Codes**	**Affected Expiration Dates**
LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers	ER320	2016-11 to 2018-03

The recall involves the following FLEX TRAY™ Procedure Delivery System product codes containing affected ER320 product:

EES Flex Tray Product Description	**Procedure Pack Product Code**	**Affected Expiration Dates**
Laparoscopic Cholecystectomy Pack	FNC42XL, KBC17XL, KNC60XL, KNC61XL, TNC20XL, TNC69XL, XCB57S, XCC50S, XCC51S, XCD50S, XCD51S	2016-12 to 2018-02

This recall involves the following Procedure Packs product codes, containing affected ER320 product:

Procedure Pack Name	**Procedure Pack Product Code**	**Affected Expiration Dates**
Laparoscopic Cholecystectomy Pack	LCHC13, LCHC15, LCHC16, LCHC17, LCHC21, LCHC23, LCHC24, LCHC25, LCHC26, LCHC27, LCHC28, LCHC29, LCHC30, LCHC32, LCHC36, LCHC38, LCHC39, LCHC42, LCHC43	**ALL**
Laparoscopic Cholecystectomy (BASX) Pack	LCHCB2, LCHCB3, LCHCB4, LCHCB6	
Laparoscopic Urology Pack	LURO1	
Laparoscopic Colon Pack	LCOL40, LCOL41, LCOL42	
Laparoscopic Gastric Bypass Pack	LGBP233, LGBP80, LGBP91	
Laparoscopic Nephrectomy Pack	LNPH11, LNPH14	
Laparoscopic Sleeve Resection Pack	LSR62	

This voluntary recall *does not apply* to the LIGACLIP® 12mm Large Endoscopic Rotating Multiple Clip Applier (product Code ER420).

Please use the Product Identification tool in **Attachment A & B** for detailed descriptions of the affected products within the specified expiration dates and for images to help identify affected products and procedure packs.

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	See Attachment C for a detailed list of product codes that can be used for substitutions.
REASON	Ethicon Endo-Surgery is initiating a voluntary recall for LIGACLIP® 10mm M/L Endoscopic Rotating Multiple Clip Applier (ER320) due to potential clip formation and feeding issues which may result in improper clip formation and insufficient occlusion of the vessel or other structure. This voluntary recall involves product code ER320 and/or Procedure Packs and/or FLEX TRAY™ Procedure Delivery Systems containing product code ER320 within the noted expiration dates.
ACTION	We need your help in ensuring that **all affected products** are located, accounted for, and returned to [Affiliate Name]. **EFFECTIVE IMMEDIATELY – DO NOT USE AFFECTED PRODUCT CODE ER320 AND/OR PROCEDURE PACKS AND/OR FLEX TRAY PROCEDURE DELIVERY SYSTEMS CONTAINING PRODUCT CODE ER320 WITHIN THE EXPIRATION DATES NOTED IN ATTACHMENT A & B.** 1) Examine your inventory immediately to determine if you have affected product on hand and **remove** the affected product. 2) Fill out the Business Reply Form and return it back to [Affiliate Name] within 3 business days, **even if you do not have affected product.** If you have product to be returned, keep a copy of this form for your records. 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: [Affiliate Name / Affiliate Address] **Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help**.
TRANS-MISSION	Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.
CONTACT	[Affiliate Name] will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form. If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name]. 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.
CONFIRM-ATION	The Field Safety Action is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and EU National Competent Authorities

ATTACHMENT A

Product Identification Tool

LIGACLIP® 10-M/L 10 mm Endoscopic Rotating Multiple Clip Appliers (ER320)

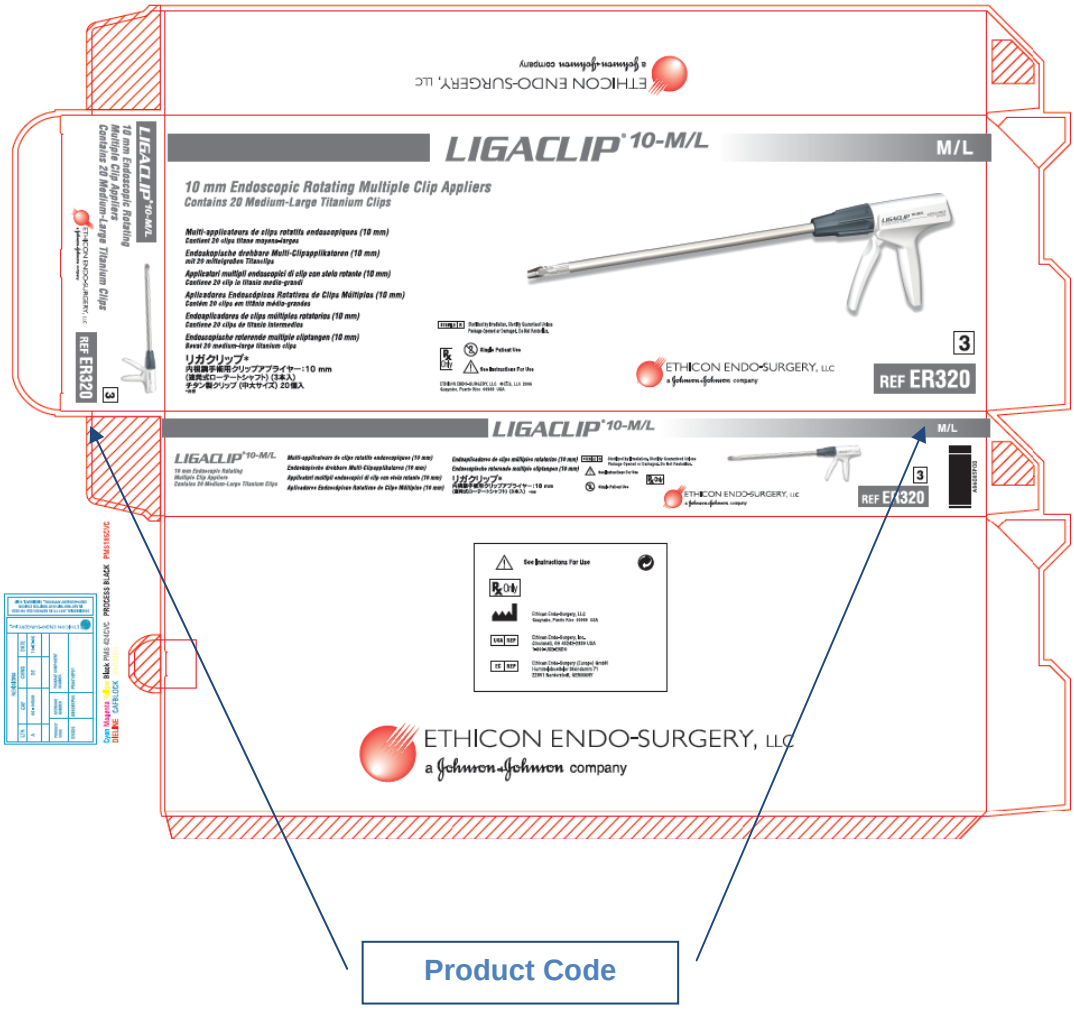
This tool will help customers identify the impacted expiration dates of product using package labels. This document applies to the secondary (single unit carton), Tyvek® primary (lidstock), and tertiary (sales unit) labels of the following product codes:

Device Name	Product Code	Affected Expiration Date
LIGACLIP® Endoscopic Rotating Multiple Clip Applier	ER320	2016-11 to 2018-03

EES Flex Tray Product Description	Procedure Pack Product Code	Affected Expiration Dates
Laparoscopic Cholecystectomy Pack	FNC42XL, KBC17XL, KNC60XL, KNC61XL, TNC20XL, TNC69XL, XCB57S, XCC50S, XCC51S, XCD50S, XCD51S	2016-12 to 2018-02

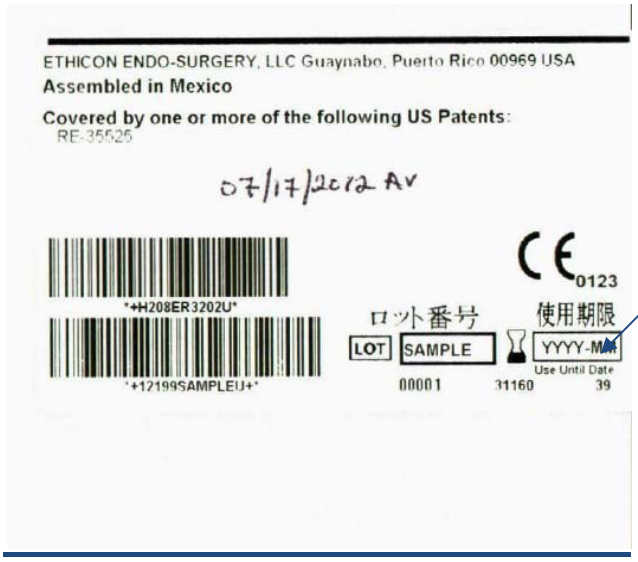
SALES UNIT CARTON (Secondary Label)

FRONT and DISPENSER PANELS



SALES UNIT LABEL

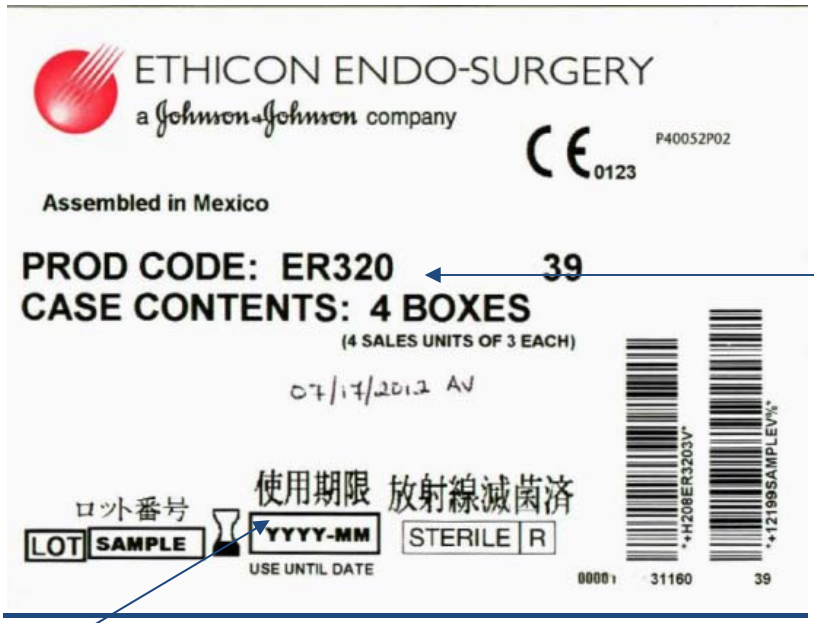
(Found on a Panel of Individual Carton)



Expiration Date

Affected Product: See Table Above

SHIPPER UNIT LABEL

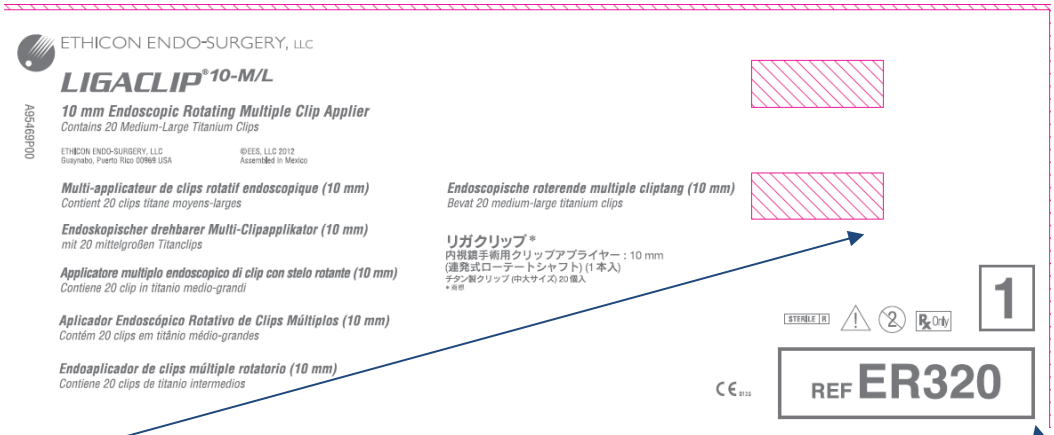


Product Code

Expiration Date

Affected Product: See Table Above

Tyvek® Single Unit Package

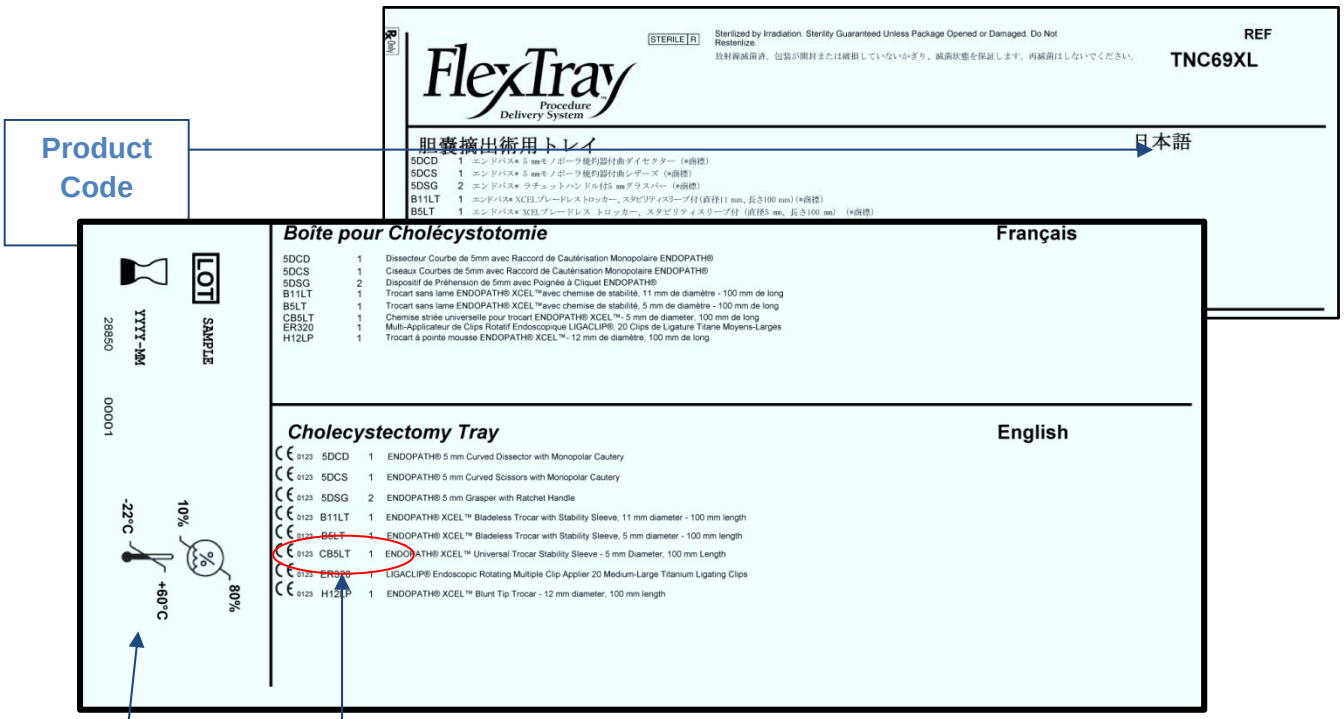


Expiration Date

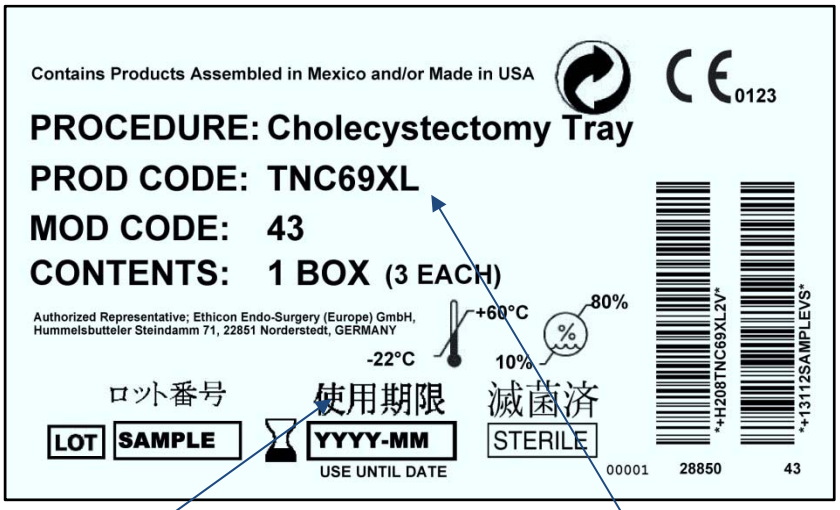
Affected Product: See Table Above

Product Code

FLEX TRAY LABEL



SHIPPER LABEL



Product Code

Expiration Date

Affected Product: See Table Above

ATTACHMENT B

Procedure Pack Product Codes and Expriy Date List

Procedure Pack Name	Procedure Pack Product Code	Affected Expiration Dates
Laparoscopic Cholecystectomy Pack	LCHC13, LCHC15, LCHC16, LCHC17, LCHC21, LCHC23, LCHC24, LCHC25, LCHC26, LCHC27, LCHC28, LCHC29, LCHC30, LCHC32, LCHC36, LCHC38, LCHC39, LCHC42, LCHC43	**ALL**
Laparoscopic Cholecystectomy (BASX) Pack	LCHCB2, LCHCB3, LCHCB4, LCHCB6	
Laparoscopic Urology Pack	LURO1	
Laparoscopic Colon Pack	LCOL40, LCOL41, LCOL42	
Laparoscopic Gastric Bypass Pack	LGBP233, LGBP80, LGBP91	
Laparoscopic Nephrectomy Pack	LNPH11, LNPH14	
Laparoscopic Sleeve Resection Pack	LSR62	

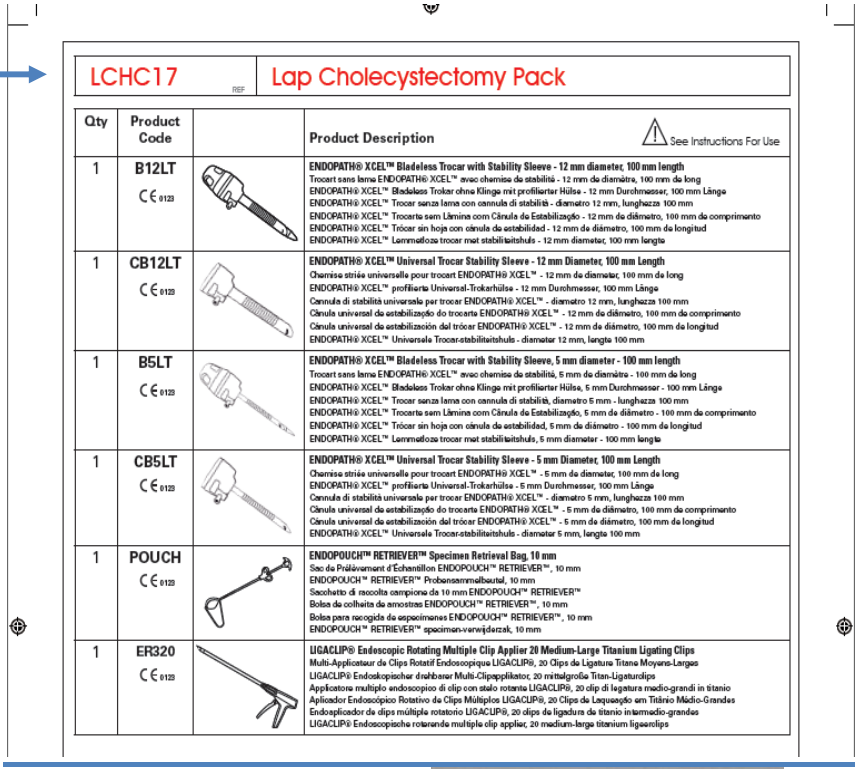
Ethicon Endo-Surgery PART OF THE Johnson & Johnson FAMILY OF COMPANIES	**Attachment B**	**REF: ER320-2013-04PP**

Procedure Pack Identification Tool

This tool will help customers identify the affected product using package labels. This applies to Procedure Pack Sales Unit Carton Label. EXAMPLE: Lap Choecystectomy Pack, product code LCHC17

Sales Unit Carton Label - LCHC17

PRODUCT CODE



LCHC17 REF Lap Cholecystectomy Pack

Qty	Product Code		Product Description (See Instructions For Use)
1	B12LT CE 0123		**ENDOPATH® XCEL™ Bladeless Trocar with Stability Sleeve - 12 mm diameter, 100 mm length** Trocart sans lame ENDOPATH® XCEL™ avec chemise de stabilité - 12 mm de diamètre, 100 mm de long ENDOPATH® XCEL™ Bladeless Trokar ohne Klinge mit profilierter Hülse - 12 mm Durchmesser, 100 mm Länge ENDOPATH® XCEL™ Trocar senza lama con cannula di stabilità - diametro 12 mm, lunghezza 100 mm ENDOPATH® XCEL™ Trocarte sem Lâmina com Cânula de Estabilização - 12 mm de diâmetro, 100 mm de comprimento ENDOPATH® XCEL™ Trócar sin hoja con cánula de estabilidad - 12 mm de diámetro, 100 mm de longitud ENDOPATH® XCEL™ Lemmetloze trocar met stabiliteitshuls - 12 mm diameter, 100 mm lengte
1	CB12LT CE 0123		**ENDOPATH® XCEL™ Universal Trocar Stability Sleeve - 12 mm Diameter, 100 mm Length** Chemise striée universelle pour trocart ENDOPATH® XCEL™ - 12 mm de diamètre, 100 mm de long ENDOPATH® XCEL™ profilierte Universal-Trokarhülse - 12 mm Durchmesser, 100 mm Länge Cannula di stabilità universale per trocar ENDOPATH® XCEL™ - diametro 12 mm, lunghezza 100 mm Cânula universal de estabilização do trocarte ENDOPATH® XCEL™ - 12 mm de diâmetro, 100 mm de comprimento Cánula universal de estabilización del trócar ENDOPATH® XCEL™ - 12 mm de diámetro, 100 mm de longitud ENDOPATH® XCEL™ Universele Trocar-stabiliteitshuls - diameter 12 mm, lengte 100 mm
1	B5LT CE 0123		**ENDOPATH® XCEL™ Bladeless Trocar with Stability Sleeve, 5 mm diameter - 100 mm length** Trocart sans lame ENDOPATH® XCEL™ avec chemise de stabilité, 5 mm de diamètre - 100 mm de long ENDOPATH® XCEL™ Bladeless Trokar ohne Klinge mit profilierter Hülse, 5 mm Durchmesser - 100 mm Länge ENDOPATH® XCEL™ Trocar senza lama con cannula di stabilità, diametro 5 mm - lunghezza 100 mm ENDOPATH® XCEL™ Trocarte sem Lâmina com Cânula de Estabilização, 5 mm de diâmetro - 100 mm de comprimento ENDOPATH® XCEL™ Trócar sin hoja con cánula de estabilidad, 5 mm de diámetro - 100 mm de longitud ENDOPATH® XCEL™ Lemmetloze trocar met stabiliteitshuls, 5 mm diameter - 100 mm lengte
1	CB5LT CE 0123		**ENDOPATH® XCEL™ Universal Trocar Stability Sleeve - 5 mm Diameter, 100 mm Length** Chemise striée universelle pour trocart ENDOPATH® XCEL™ - 5 mm de diamètre, 100 mm de long ENDOPATH® XCEL™ profilierte Universal-Trokarhülse - 5 mm Durchmesser, 100 mm Länge Cannula di stabilità universale per trocar ENDOPATH® XCEL™ - diametro 5 mm, lunghezza 100 mm Cânula universal de estabilização do trocarte ENDOPATH® XCEL™ - 5 mm de diâmetro, 100 mm de comprimento Cánula universal de estabilización del trócar ENDOPATH® XCEL™ - 5 mm de diámetro, 100 mm de longitud ENDOPATH® XCEL™ Universele Trocar-stabiliteitshuls - diameter 5 mm, lengte 100 mm
1	POUCH CE 0123		**ENDOPOUCH™ RETRIEVER™ Specimen Retrieval Bag, 10 mm** Sac de Prélèvement d'Echantillon ENDOPOUCH™ RETRIEVER™, 10 mm ENDOPOUCH™ RETRIEVER™ Probensammelbeutel, 10 mm Sacchetto di raccolta campione da 10 mm ENDOPOUCH™ RETRIEVER™ Bolsa de colheita de amostras ENDOPOUCH™ RETRIEVER™, 10 mm Bolsa para recogida de especímenes ENDOPOUCH™ RETRIEVER™, 10 mm ENDOPOUCH™ RETRIEVER™ specimen-verwijderzak, 10 mm
1	ER320 CE 0123		**LIGACLIP® Endoscopic Rotating Multiple Clip Applier 20 Medium-Large Titanium Ligating Clips** Multi-Applicateur de Clips Rotatif Endoscopique LIGACLIP®, 20 Clips de Ligature Titane Moyens-Larges LIGACLIP® Endoskopischer drehbarer Multi-Clipapplikator, 20 mittelgroße Titan-Ligaturclips Applicatore multiplo endoscopico di clip con stelo rotante LIGACLIP®, 20 clip di legatura medio-grandi in titanio Aplicador Endoscópico Rotativo de Clips Múltiplos LIGACLIP®, 20 Clips de Laqueação em Titânio Médio-Grandes Endoaplicador de clips múltiple rotatorio LIGACLIP®, 20 clips de ligadura de titanio intermedio-grandes LIGACLIP® Endoscopische roterende multiple clip applier, 20 medium-large titanium ligeerclips

PRODUCT CODE

LOT NUMBER

Assembler:

Ethicon Endo-Surgery (Europe) GmbH
Hummelsbütteler Steindamm 71
D-22851 Norderstedt, Germany

Refer to single procedure pack components to identify legal manufacturer and sterilization method.

ITEM: LCHC17

LOT: 114984

EXPIRY: 2017-09-30

MANUFACTURE: 2013-01-03

ENDOPATH® XCEL™ ACCESS SYSTEM

PROCEDURAL PACK ETHICON ENDO-SURGERY a Johnson & Johnson company

LURO1-LAT-01 / CO-0018492

ETHICON PART OF THE Johnson & Johnson FAMILY OF COMPANIES	**Business Reply Form**	**REF: ER320-2013-04; ER320-2013-04PP**

Your timely response to this recall notification is requested. Please fill out and mail or fax this form to [Local Affiliate Address and Fax number] within 3 business days **even if you do not have product to return.** If you have affected product to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

☐ **No, we do not have affected product for return.**

☐ **Yes, we do have affected product for return (complete list below).**

Lot Number	Product Code	Product Description	Units on Hand

Name/Signature/Date

Facility Name

Customer Number