ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

[Date]

URGENT: FIELD SAFETY NOTIFICATION

GYNECARE INTERCEED™ Clinical Study Results

Product Code	Product Description	GTIN	Lot
M4350	GYNECARE INTERCEED 3INX4IN(7.6CMX10.2CM)	10705031062740	All Lot Numbers
M4345	GYNECARE INTERCEED 3INX4IN(7.6CMX10.2CM)	10705031062429	All Lot Numbers

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE GYNECARE INTERCEED™

Dear Healthcare Provider,

At Ethicon, our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products. Ethicon has initiated a voluntary field safety notification to inform health care providers of recent clinical study results in patients undergoing two-phase laparoscopic colorectal surgery results for GYNECARE INTERCEED™ Absorbable Adhesion Barrier.

Reason for Field Safety Notification

A multi-center, randomized clinical study was recently conducted to evaluate the effect of INTERCEED™ in preventing abdominal adhesions in patients with colorectal carcinoma undergoing two-phase laparoscopic hand-assisted colorectal resection. The primary study objective was to evaluate the safety and efficacy of INTERCEED™ in laparoscopic colorectal surgery to reduce incidence of adhesions at the abdominal incision site.

The results of the clinical study interim analysis show that the incidence of adhesions at the target incision site were similar between the two study groups: INTERCEED™ vs. Control (No Adhesion Barrier). The study was terminated due to the lack of expected superior efficacy for INTERCEED™ as compared to Control (No Adhesion Barrier). No new safety issues were identified. **See Appendix 1 for study design and interim analysis results.**

Indications and clinical use

INTERCEED™ is currently indicated *as an adjuvant in general abdominal and gynecological pelvic surgery for reducing the incidence, extent and severity of postoperative abdominal adhesions after meticulous hemostasis has first been achieved. The safety and efficacy of the product in reducing postoperative adhesions in areas other than the open (laparotomy) gynecological field has not yet been clinically tested.*"

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Based on the results of the interim analysis for this prospective study, Ethicon is sending this Field Safety Notification to inform CE-mark INTERCEED customers about the results in patients undergoing two phase laparoscopic hand-assisted colorectal surgery. In addition, Ethicon is working with our European Notified Body and other Health Authorities to narrow the scope of our approved indications from "…an adjuvant in general abdominal and gynaecological pelvic surgery…" to "…an adjuvant in open (laparotomy) gynecological pelvic surgery…" and revise the Instructions for Use accordingly.

Actions for Health Care Providers

There is no new product safety impact or risk of patient harm identified in the study results. Due to the lack of demonstrated superior efficacy in preventing abdominal adhesions in patients with colorectal carcinoma undergoing two-phase laparoscopic hand-assisted colorectal resection when using INTERCEED versus not using an adhesion barrier, Healthcare professionals should consider these study results in determining treatment of patients during abdominal procedures other than pelvic gynecological procedures. Health care practitioners who have treated patients using this product according to its prescribing information should follow those patients post-operatively in the usual manner with no additional action required.

The study results **do not** impact or affect the safe and effective use of INTERCEED™ in open gynecologic procedures.

Actions To Be Taken

Our records indicate that you may have ordered or received product subject to this field safety notification and we ask you to please take the following actions:

- Forward this notice to all surgeons in your facility using these devices.
- Keep a copy of this notice with the subject product.
- If any of the subject product has been forwarded to another facility, contact that facility
- Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return to [Insert Affiliate Information] within three (3) business days. Please return the BRF even if you do not have product subject to this field safety notification.

Ethicon is working with local health authorities to update the Instructions for Use (IFU) to reflect the outcome of this clinical study. If you have questions or concerns with regards to this field safety notification, please contact [Insert contact information]. We apologize for any inconvenience this action may cause and thank you for your cooperation.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

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Appendix 1

Prospective, Multicenter, Randomized Study to Evaluate the Effect of INTERCEED™ Absorbable Adhesion Barrier in Preventing Abdominal Adhesions

Study Objective: To evaluate the safety and efficacy of INTERCEED™ in reducing the incidence of adhesions at the target incision site in patients undergoing two-phase laparoscopic colorectal surgery

Study Design

- Planned to enroll 220 subjects in 1:1 ratio (INTERCEED™ vs. Control - no adhesion barrier)
- Phase 1 operation: laparoscopic radical resection of colo- rectal carcinoma with temporary ileostomy
- INTERCEED™ was applied beneath the target incision site (the midline incision for hand assisted removal of the specimen)
- Phase 2 operation: subjects to return 3-9 months after the phase 1 operation to have ileostomy reversal

Primary Endpoint: Proportion of subjects with adhesions at the target incision site in each study group

The assessment of adhesions conducted during the 2nd laparoscopy for ileostomy reversal reviewing the video imaging data by independent central reviewers blinded to the study treatment groups.

An ad-hoc interim analysis was planned to be performed while at least 61% of the total number of participants with evaluable primary endpoints available. If the conditional power (CP) is ≤ 60% and the observed adhesion rate difference magnitude was much less than the assumed difference magnitude of 0.25, the study should be terminated due to low incidence of adhesions and small effect size between INTERCEED and Control arms.

An independent Data Monitoring Committee (DMC) in China reviewed the interim analysis results from 171 subjects enrolled as of November 2020 and recommended that the study should be terminated because the pre-specified stopping criterion was met. The ETHICON independent review board agreed with DMC recommendation.

The incidence of adhesions at the target incision site were similar between the study groups, INTERCEED (14.9%) vs. Control (16.0%), and the study was terminated because of the lack of expected superior efficacy for the study product. No new safety signals/issues were identified in this study.

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Attachment 2: Business Reply Form

Business Reply Form (BRF)

Your timely response to this field safety notification is requested. Please complete this form and fax or email it to [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] **within 3 business days, even if you do not have product subject to this field safety notification.**

Thank you for your cooperation.

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

By signing and returning this business reply form we acknowledge the receipt of this notification.