



Disposable Medical Devices

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Omnia Srl - Via F. Delnevo, 190 sk
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tel +39 0524 527453 - fax +39 0524 525230
Cod. Fisc./Part. IVA/Reg.Imp.: IT 01711860344
R.E.A. PR 173685 - Capitale sociale i.v. € 200.000,00

Dringend – Produktrückruf - Erste Benachrichtigung

Datum: 22 September 2020

Produkt: Cardinal Health Protexis Latex Micro chirurgische Handschuhe

Begründung des Rückrufs

Mit diesem Schreiben möchten wir Sie darüber informieren, dass Cardinal Health, Hersteller von Protexis Latex Micro chirurgischen Handschuhen, uns über einen freiwilligen Rückruf bestimmter Handschuhe informiert hat. Die Protexis Latex Micro chirurgischen Handschuhe werden von Omnia in Sets verwendet. Wegen einer Materialschwächung an den chirurgischen Handschuhen, der zu Löchern und Rissen im Faltbereich der Manschette führen kann, wird ein Rückruf durchgeführt. Informationen über den Rückruf von Cardinal Health finden Sie im Anhang dieser Benachrichtigung.

Produktinformation zum Rückruf:

Katalognummer	Beschreibung	Lotnummer
12.I0989.00	Implantologieset	193021
12.E2614.00	Implantologieset	193107
12.I0909.00	Implantologieset	193115; 200826
12.I0035.00	Chirurgisches Kit	193110; 200314
12.E2103.00	Implantologieset	193105; 202503
12.E1885.00	Implantologieset	193102; 202502
12.E1886.00	Implantologieset	193103
12.E2464.00	Implantologieset	193206; 200530
12.S9666.00	Chirurgisches Kit	193221
12.I0993.00	Implantologieset	193406
12.E0228.00	Implantologieset	193430
12.E0232.00	Implantologieset	193524
12.E0074.00	Implantologieset	193523
12.S9665.00	Chirurgisches Kit	193513
12.S1267.00	Implantologieset	193617
12.S9414.00	Chirurgisches Kit	193720
12.E2532.00	Implantologieset	193809
12.S9665.00	Chirurgisches Kit	202821
12.E0228.00	Implantologieset	202901
12.I1111.00	Implantologieset	203004; 201009; 203004
12.T3055.00	Implantologieset	203229; 200503
12.I0237.00	Implantologieset	203302
12.E2275.00	Implantologieset	193106; 202504
12.I1008.00	Implantologieset	193301
12.I1003.00	Implantologieset	193323
12.I0334.00	Implantologieset	193722
12.E3111.00	Implantologieset	193713
12.I0707.00	Implantologieset	200104

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FDA Establishment n. 3004361903



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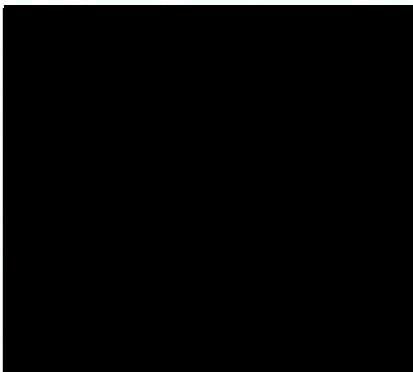
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12.E0507.00	Implantologieset	200203
12.E3165.00	Implantologieset	200121
12.E0557.00	Implantologieset	200502
12.E3237.00	Implantologieset	200721
12.E3319.00	Implantologieset	202506
12.E3321.00	Implantologieset	202509
12.E2615.00	Implantologieset	202505
12.E3320.00	Implantologieset	202507
12.I1099.00	Implantologieset	202912

Schritte für Händler/Importeure/Endkunden

1. Überprüfen Sie Ihr Inventar anhand der oben aufgeführten Katalog- und Lotnummern.
2. Im Falle eines Weiterverkaufs des Produktes, informieren Sie bitte Ihre(n) Kunden über diesen Rückruf und fordern Sie die Rücksendung des betroffenen Produkts an.
3. Füllen Sie das beigefügte Bestätigungsformular aus, indem die Katalognummern (A), Lotnummern (B), die Gesamtzahl der betroffenen Einheiten, die an Omnia S.R.L. (C) zurückgesandt werden, sowie Ihre Einrichtung und Kontaktinformationen angegeben sind.
4. Leiten Sie das Bestätigungsformular per E-Mail an alessandra.cesari@omniaspa.eu oder per Fax unter (+39) 524-525230 an Alessandra Cesari weiter. Bitte senden Sie das beigefügte Formular zurück, auch wenn das Produkt von Ihnen oder Ihrem Kunden konsumiert wurde (in diesem Fall geben Sie in Spalte (C) bitte 0 an).
5. Wenn Sie alle in (C) aufgeführten Einheiten gesammelt haben, senden Sie sie bitte mit dem Hinweis **RÜCKRUF 01/2020 - att. Alessandra Cesari** an Omnia S.R.L. zurück.

Wir entschuldigen uns für die entstandenen Unannehmlichkeiten.



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Bestätigungsformular - Cardinal Health Protexis Latex Micro Chirurgische Handschuhe

A	B	C
Katalognummer(n)	Lotnummer(n)	Gesamtzahl der betroffenen Einheiten zur Rücksendung an Omnia S.R.L.

Firmenname: _____

Name: _____

Unterschrift: _____

Datum: _____

Land: _____

Telefonnr.: _____

Faxnr.: _____

E-Mail: _____

Bitte senden Sie dieses Formular per E-Mail an alessandra.cesari@omniaspa.eu oder per Fax an (+39) 524-525230.

Wenn Sie Fragen haben, können Sie uns auch telefonisch unter (+39) 524-52745 erreichen.

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URGENT: FIELD SAFETY NOTICE (Removal)

Specific product codes and lots of:

- **Protexis Latex Micro Surgical Gloves**

Event-2020-03063

29 July 2020

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is voluntarily recalling specific production lots of **Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves** that were distributed between June 2019 and July 2020.

Issue Description

This recall is being conducted due to a degradation defect that was found on **Cardinal Health™ PROTEXIS™ Latex Micro Surgical Gloves** that could lead to holes and donning tears at the folding area around the cuffs (Refer to exhibit B for examples of the defect) with the potential risk of infection or cross-patient (clinician) exposure to body fluids. Cardinal Health is not aware of any reports of patient harm.

Cardinal Health is initiating this voluntary recall on the following item codes and lot numbers:

Item Code	Item Description	Lot No.
2D72NT55X	PROTEXIS™ Latex Micro Surgical Gloves Size 5.5	TS19060034, TS19060253, TS19060338, TS19070077, TS19070176, TS19070246, TS19070318, TS19080036, TS19080091, TS19080137, TS19090125, TS19090164, TS19090248, TS19100272, TS19110080, TS19110205, TS19110313, TS19120119, TS19120120, TS20010146, TS20010214, TS20020201, TS20020202, TS20030154, TS20030155, TS20030279, TS20040092, TS20040093, TS20040248
2D72NT60X	PROTEXIS™ Latex Micro Surgical Gloves Size 6.0	TS19060010, TS19060043, TS19060123, TS19060199, TS19060234, TS19070005, TS19070027, TS19070067, TS19070130, TS19070179, TS19070245, TS19070273, TS19080030, TS19080092, TS19080119, TS19080124, TS19080208, TS19080211, TS19080300, TS19080329, TS19090067, TS19090158, TS19090226, TS19090289, TS19100051, TS19100085, TS19100172, TS19100240, TS19100300, TS19110022, TS19110079, TS19110184, TS19110207, TS19110333, TS19120019, TS19120083, TS19120213, TS19120322, TS20010037, TS20010094, TS20010191, TS20010202, TS20010258, TS20010329, TS20020121, TS20020209, TS20030015, TS20030092, TS20030093, TS20030172, TS20030264, TS20030265, TS20030324, TS20040033, TS20040137
2D72NT65X	PROTEXIS™ Latex Micro Surgical Gloves Size 6.5	TS19060012, TS19060037, TS19060064, TS19060118, TS19060140, TS19060158, TS19060235, TS19060257, TS19060303, TS19060340, TS19060393, TS19070019, TS19070068, TS19070084, TS19070138, TS19070185, TS19070231, TS19070247, TS19070297, TS19070317, TS19080022, TS19080040, TS19080051, TS19080093, TS19080110, TS19080128, TS19080134, TS19080209, TS19080239, TS19080258, TS19080269, TS19080326, TS19090044, TS19090058, TS19090104, TS19090200, TS19090212, TS19090262, TS19090295, TS19100043, TS19100099, TS19100138, TS19100173, TS19100221, TS19100280, TS19100310, TS19110023, TS19110058, TS19110076, TS19110083, TS19110150, TS19110211, TS19110349, TS19120020, TS19120073, TS19120084, TS19120233, TS19120323, TS20010017, TS20010048, TS20010072, TS20010109, TS20010166, TS20010193, TS20010265, TS20010306, TS20020024, TS20020098, TS20020108, TS20020149, TS20020247, TS20020248, TS20020262, TS20030066, TS20030078,



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		TS20030179, TS20030191, TS20030219, TS20030220, TS20030318, TS20030325, TS20040039, TS20040116, TS20040175, TS20040259
2D72NT70X	PROTEXIS™ Latex Micro Surgical Gloves Size 7.0	TS19060002, TS19060036, TS19060115, TS19060216, TS19060238, TS19060258, TS19060274, TS19060339, TS19070029, TS19070092, TS19070108, TS19070180, TS19070285, TS19070320, TS19080035, TS19080037, TS19080064, TS19080138, TS19080140, TS19080186, TS19080210, TS19080257, TS19080271, TS19080320, TS19090004, TS19090054, TS19090126, TS19090149, TS19090263, TS19090266, TS19100058, TS19100107, TS19100186, TS19100253, TS19100308, TS19110026, TS19110038, TS19110068, TS19110090, TS19110157, TS19110225, TS19110324, TS19120005, TS19120056, TS19120109, TS19120141, TS19120161, TS19120162, TS19120257, TS19120258, TS19120299, TS20010002, TS20010051, TS20010085, TS20010129, TS20010184, TS20010246, TS20010247, TS20010305, TS20020074, TS20020075, TS20020140, TS20020146, TS20020223, TS20020227, TS20020284, TS20030094, TS20030165, TS20030166, TS20030227, TS20030228, TS20030299, TS20040045, TS20040046, TS20040130, TS20040197, TS20040139, TS20040367, TS20050112, TS20050158
2D72NT75X	PROTEXIS™ Latex Micro Surgical Gloves Size 7.5	TS19060031, TS19060065, TS19060081, TS19060129, TS19060168, TS19060302, TS19070161, TS19070201, TS19070229, TS19080080, TS19080176, TS19080203, TS19080262, TS19090027, TS19090064, TS19090167, TS19090272, TS19100068, TS19100111, TS19100197, TS19100244, TS19100262, TS19110041, TS19110102, TS19110176, TS19110238, TS19110314, TS19120002, TS19120044, TS19120093, TS19120166, TS19120274, TS19120275, TS19120298, TS20010009, TS20010064, TS20010070, TS20010155, TS20010217, TS20010255, TS20010315, TS20020092, TS20020115, TS20020161, TS20020162, TS20020236, TS20020237, TS20020286, TS20030110, TS20030111, TS20030192, TS20030215, TS20030240, TS20030288, TS20040029, TS20040030, TS20040086, TS20040147, TS20050114, TS20050115
2D72NT80X	PROTEXIS™ Latex Micro Surgical Gloves Size 8.0	TS19060053, TS19060095, TS19060169, TS19060273, TS19060328, TS19060357, TS19070100, TS19080183, TS19080200, TS19080225, TS19080308, TS19090043, TS19090188, TS19090292, TS19100150, TS19100214, TS19100269, TS19100282, TS19110056, TS19110050, TS19110115, TS19110249, TS19110295, TS19110334, TS19120049, TS19120122, TS19120215, TS19120308, TS19120309, TS20010031, TS20010103, TS20050122, TS20050165
2D72NT85X	PROTEXIS™ Latex Micro Surgical Gloves Size 8.5	TS19060044, TS19060122, TS19060189, TS19060356, TS19080111, TS19080184, TS19080227, TS19080321, TS19090008, TS19090127, TS19100079, TS19100220, TS19100271, TS19100309, TS19110075, TS19110069, TS19110109, TS19110148, TS19110285, TS19110331, TS19120038, TS19120118, TS19120214, TS19120316, TS19120317, TS20010036, TS20010093, TS20050031, TS20050139
2D72NT90X	PROTEXIS™ Latex Micro Surgical Gloves Size 9.0	TS19080275, TS19090162, TS19090231, TS19110286, TS19120251, TS20010216, TS20030153

This FSCA affects only the specific combinations of item codes and lots listed above. The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action. We request that you contact Cardinal Health if you have experienced quality problems or adverse events.

Required Actions:

1. **CHECK all storage and usage locations to confirm whether you have any units of the affected product codes and lot numbers. Exhibit A outlines examples of product labeling and how to identify the affected product. Exhibit B outlines the location of the defect.**
2. **Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form.**
3. **Return all affected product or contact your local sales representative to facilitate return of the affected product. Your sales representative will inform you of the product replacement or credit options.**



CardinalHealth

4. **Share this letter with others in your facility who need to be made aware of this recall. Contact any other facilities that have been provided with units of affected lot.**
5. **Maintain awareness of this notice until all affected product has been returned to Cardinal Health.**
6. **Keep a copy of this notice with any affected product until returned.**

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your local sales representative or local sales office.

Sincerely,



EXHIBIT A – Packaging of Affected Product

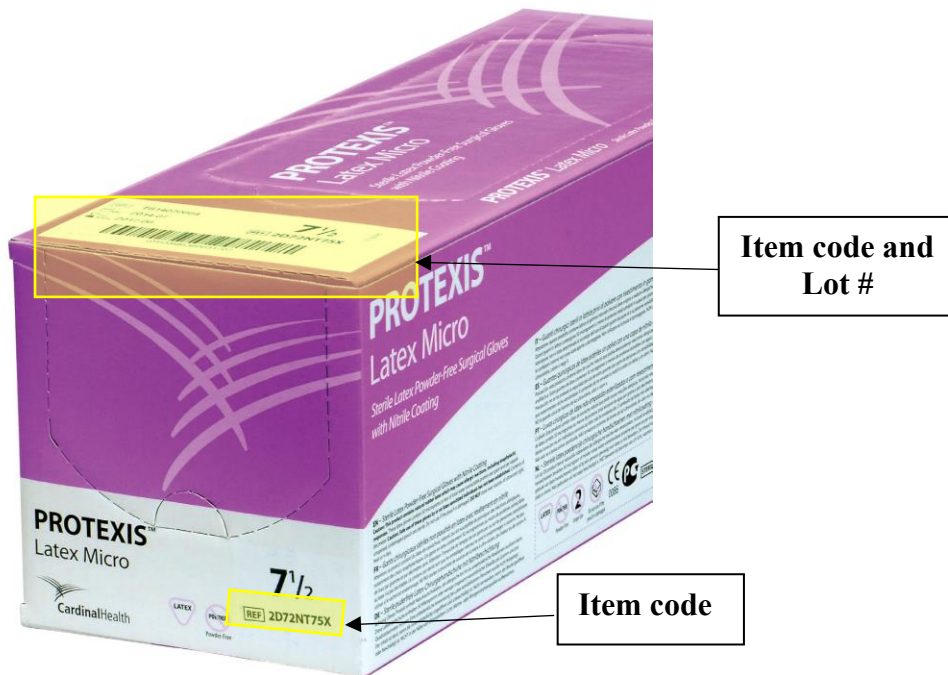
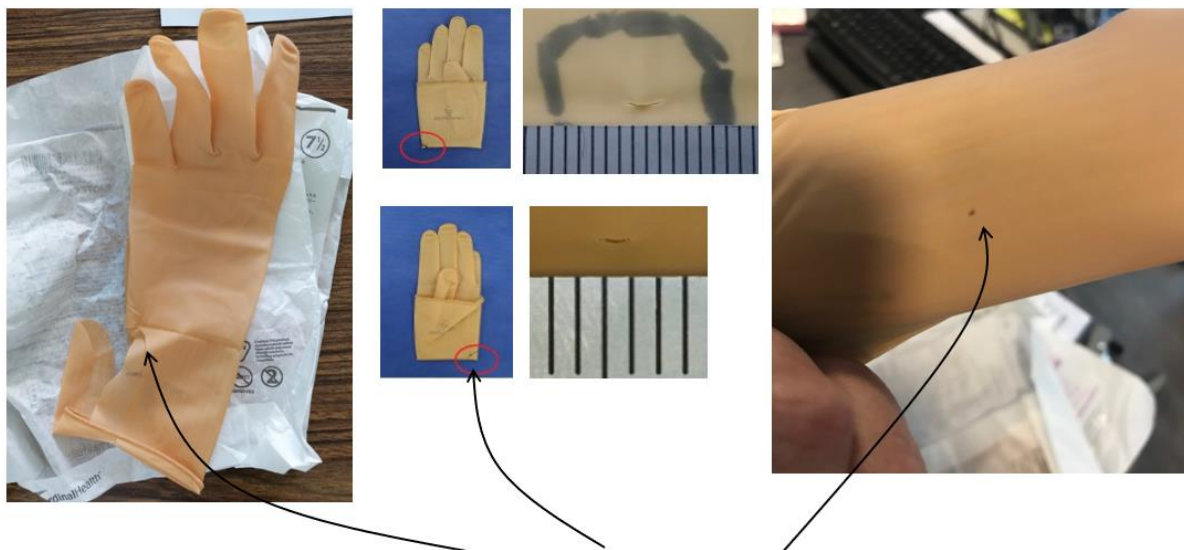


Exhibit B: Examples of the defect



Degradation defect found at cuff (folding area).