Medline International France
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh
44 110 Châteaubriant

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Châteaubriant, 21st July 2026

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical/Engineering Department

Security information for Use of Med-Stop Devices withing Soft Liner Suction Canister Kits

Medline Reference:	**FSN-26/08**
CA Reference:	**To be Defined**
Product description:	Medline Soft Liner with Suction Tubing and Med-Stop Vacuum Controller Kits combine a Soft Liner with a non-sterile ORNEX style Suction Tubing equipped with a pre-attached non-sterile Med-Stop Vacuum Controller (herein referred to in combination as the Soft Liner Med-Stop Kit). The Med-Stop Vacuum Controller is a manual fingertip control vacuum valve used to manually control suction, which is utilized in the operating room during surgical procedures and aides in the suctioning of fluid from the patient's body. Med-Stop is connected to a suction tubing on one end and a suction catheter at the other end. This setup is connected to the Soft Liner's 'Patient Port', to then suction fluid from the patient. All Medline Suction Canister Systems are intended to be used in the healthcare environment by healthcare professionals during procedures that require the collection of fluid, which may accumulate or must be contained and removed during the procedure. Medline Suction Canister System's intended for use on patients, within the general patient population, undergoing a procedure to sample, aspirate, or remove bodily fluids.
Legal Manufacturer SRN:	**US-MF-000009717**
Action type:	**Field Safety Notice**
Product codes:	**See Appendix 1 (page 6)**

Dear Customer,

This letter is to advise you that Medline Industries LP has initiated a Field Safety Notice regarding the instructions for use of the Med-Stop devices included within Soft Liner Suction Canister kits. All impacted product codes for this Field Safety Notice are listed in Appendix 1 (page 7) attached hereto.

Medline has decided to notify all customers who have received these impacted products mentioned in Appendix 1 (page 6).

Appendix 2 to this FSN-26/08 (page 7) contains the Med-Stop device Instructions for Use (IFU) which shall be included in future Soft Liner Suction Canister kits containing a Med-Stop device. The purpose of this Field Safety Notification is to address the omission of the Instructions for Use (IFU) from the Med-Stop Device in Soft Liner Suction Canister kits by providing the missing IFU and ensuring users have access to the complete product information.

REASON FOR THE FIELD SAFETY NOTICE:

It has been identified that the current labeling of Soft Liner Suction Canister kits with Med-Stop Devices do not contain the Med-Stop IFU

As a corrective measure, Medline will be providing Med-Stop Instructions for Use (IFU) with Soft Liner Suction Canister kits which include Med-Stop Devices.

Future Soft Liner Suction Canister kits with a Med-Stop Device will now contain a Med-Stop Device IFU in addition to the Suction Canister System IFU. Following this FSN, the Suction Canister System IFU will also be updated to include reference to the co-packaged Med-Stop Device IFU for applicable product codes.

HEALTH RISK:

Improper use of the Suction Canister System with a Med-Stop device, may result in:

- Contamination and increased risk of infection
- Reduced or impaired device performance/function
- Device malfunction or failure during use

These conditions may ultimately lead to patient injury, illness, and/or, in severe cases, death.

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

IMPORTANT SAFETY INFORMATION AND RISK MITIGATION MEASURES:

The additional IFU for the Med-Stop device (Appendix 2, page 7) forms part of this Field Safety Notice FSN-26/08 and should be reviewed together with the safety information provided below. Continued production of the impacted products listed in Appendix 1 (page 6) will now include the Med-Stop IFU.

Safety Information associated with Soft Liner Suction Canister kits containing a Med-Stop Device:

- Consult the Med-Stop Instructions for Use (IFU) for set-up, use, and rinsing of the Med-Stop Device in conjunction with the Soft Liner Suction Canister system.

ACTIONS REQUIRED:

Step 1: Please take note of this safety information and inform all users in your facility.

Step 2: Please ensure that the Instructions for Use (IFU) is distributed to all relevant users and retained with the impacted products. Please note that this leaflet will accompany future product shipments that are impacted by this FSN-26/08 until the updated Instructions for Use (IFU) become available.

Step 3: Please complete the **Acknowledgment Receipt (page 5)** and confirm that the **MedStop Instruction for Use will be implemented at your facility.** Then, return page 5 by email as soon as possible **but no later than 17th August 2026.**

Step 4: If you no longer have any of the impacted products in stock, please also complete the **Acknowledgment Receipt** (page 5) and return it by email as soon as possible **but no later than 17th August 2026.**

Step 5: If you have any questions or need support with finding alternative solutions, please contact your Medline Sales Representative or your local Medline Customer Service.

The relevant competent authorities have been informed of this FSN.
Please proceed to the following pages to acknowledge receipt of this FSN. Medline apologizes for the inconvenience this matter may cause and would like to thank you for your cooperation and prompt attention to this notice.

Yours sincerely,
Willem van Alst,
Sr. Manager Post Market Surveillance, Medline EMEA

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

Transmission of this FSN:

This urgent and important field safety notice is only addressed to facilities that have received (or may receive) the impacted products.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

* * *

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

Please email the Acknowledgement Receipt to the following email address:
GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSN-26/08

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than 17th August, 2026**.

Medline's Soft Liner Suction Canister Kits, in which the Med-Stop Devices are included, are listed in the table in **Appendix 1** (*page 6*).

By completing and signing the document, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-26/08 by signing this document and returning it to Medline.

I also agree to further distribute and communicate this important information within my facility as required.

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are **a dealer, wholesaler, distributor/reseller**, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above.

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

Appendix 1 – Product Codes concerned

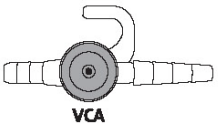
Reference	Item description	Lot number	Unique Device Identifier
OR53916	Soft Suction Liner 1000cc with 1.8m x 6mm tubing and adult vacuum control	All	UDI-DI: 0888277DC265NSKX
OR53926	Soft Suction Liner 1500cc with 1.8m x 6mm tubing and adult vacuum control		
OR53929	Soft Suction Liner 1500cc with 3.0m x 6mm tubing and adult vacuum control		
OR54916	Soft Suction Liner 1000cc with 1.8m x 6mm tubing and pediatric vacuum control		
OR54926	Soft Suction Liner 1500cc with 1.8m x 6mm tubing and pediatric vacuum control		

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

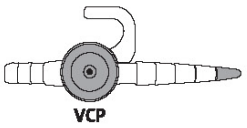
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

MED-STOP
Vacuum Control Valve
Instructions for use

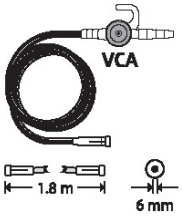
de **MED-STOP Vakuumkontrolle Verbindungsstück** - Gebrauchsanweisung
fr **Valve de contrôle de vide MED-STOP** - Mode d'emploi
nl **MED-STOP Vacuüm Controleklep** - Gebruiksaanwijzing
it **MED-STOP valvola per controllo del vuoto** - Istruzioni per l'uso
es **Válvula de control de vacío MED-STOP** - Instrucciones de uso
pt **Válvula de Controlo de Vácuo MED-STOP** - Instruções para Uso
sk **MED-STOP Vákuový regulačný ventil** - Návod na použitie
cs **Vakuový řídicí ventil MED-STOP** - Návod k použití
sv **MED-STOP vakuumkontrollventil** - Instruktioner för användning
fi **MED-STOP -imun säätöventtiili** - Käyttöohjeet
da **MED-STOP Vakuumkontrolventil** - Instruktion
no **MED-STOP vakuumstopp kontroll ventil** - Bruksanvisning
el **Βαλβίδα ελέγχου κενού MED-STOP** - Οδηγίες χρήσης
pl **Zawór MED-STOP do kontroli podciśnienia** - Instrukcja obsługi
sl **Ventil za regulacijo vakuuma MED-STOP** - Navodila za uporabo
ro **Supapă de control aspirație MED-STOP** - Instructiuni de folosire
bg **Вентил за управление на вакуума MED-STOP** - Инструкции за употреба
et **MED-STOP vaakumjuhtventiil** - Kasutusjuhised
hu **MED-STOP vákuumszabályozó szelep** - Használati utasítás
lt **MED-STOP vakuuminis valdymo vožtuvas** - Naudojimosi instrukcijos
hr **MED-STOP ventil za regulaciju vakuuma** - Upute za uporabu
tr **MED-STOP Vakum Kontrol Valfi** - Kullanim talimatlari
ar **MED-STOP صمام التحكم في التفريغ الهوائي** - تعليمات الاستخدام



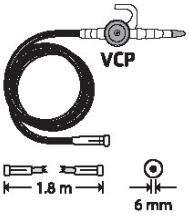
REF OR853VCA



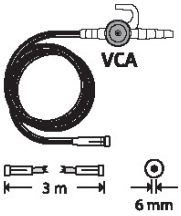
REF OR854VCP



REF ORNEX66VCA



REF ORNEX66VCP



REF ORNEX610VCA

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

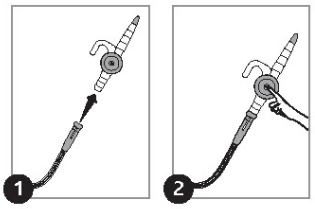
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

en MED-STOP Vacuum Control Valve

OR853VCA .....MED-STOP, Adult Manual Vacuum Controller
OR854VCP .....MED-STOP, Pediatric Manual Vacuum Controller
ORNEX66VCA .....ORNEX Suction Tubing (1.8m) + Adult MED-STOP Control Valve
ORNEX66VCP .....ORNEX Suction Tubing (1.8m) + Pediatric MED-STOP Control Valve
ORNEX610VCA .....ORNEX Suction Tubing (3m) + Adult MED-STOP Control Valve

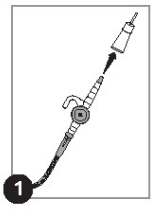
Indication for Use:

1. **MED-STOP Vacuum Control Valve** ***Setup***



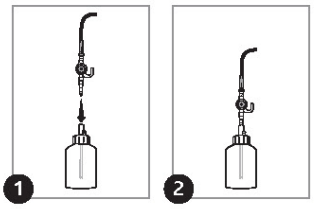
a. Connect the MED-STOP Vacuum Control Valve to the suction tubing.
b. Proceed to rinse the device by suctioning sterile saline or sterile water to verify device functionality to ensure proper operation before patient application.
c. MED-STOP is ready for use.

2. **MED-STOP Vacuum Control Valve** ***Use***



a. Connect the MED-STOP Vacuum Control Valve to the suction catheter and proceed with suction.
b. To manually apply suction, cover the open hole on the blue cover with a finger.
c. When the suction system and connected MED-STOP are not in use during a procedure, ensure the vacuum is turned off.
d. *Refer to rinsing during use section to prevent blockage from suctioned material.*

3. **MED-STOP Vacuum Control Valve** ***Rinsing During Use***



a. Carefully remove the suction catheter and insert the MED-STOP Vacuum Control Valve in the cleaning bottle cap.
b. Rinse the device during use by suctioning sterile saline or sterile water, as clinically indicated, to maintain system patency and prevent blockage from secretions, mucus, or other material. Replace the device if obstructions cannot be cleared.

No need to follow STEP 1 for ORNEX + MED-STOP set (ORNEX66VCA, ORNEX66VCP and ORNEX610VCA).

Contraindications:

Do **NOT** use if the valve does not work correctly.

⚠ Important:

- Reuse of single use devices creates a potential risk for the patient or user. It may cause contamination and/or impairment of function, which may lead to injury, illness and/or death.
- If a serious incident occurs in relation to the use of the device, it should be reported to Medline and relevant competent authorities of the Member State in which the user and/or patient is established.
- Single-use device — Do not reuse. Discard the device after the procedure in accordance with facility protocol and use a new MED-STOP device for each new procedure.
- Intended for use during single suction procedures.
- Use only by trained healthcare professionals familiar with suction equipment.
- Prior to use, visually inspect valve for obstructions or particulate. Do not use the product if obstructions or particulate matter are present; discard the product in accordance with local procedures.
- Prior to use, rinse the device by suctioning sterile saline or sterile water to verify device functionality to ensure proper operation before patient application.
- Rinse the device during use by suctioning sterile saline or sterile water, as clinically indicated, to maintain system patency and prevent blockage from secretions, mucus, or other material. Replace the device if obstructions cannot be cleared.
- When the suction system and connected MED-STOP are not in use during a procedure, ensure the vacuum is turned off.

2

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

ORNEX + MED-STOP (ORNEX66VCA, ORNEX66VCP, ORNEX610VCA)

DEHP warning: This product contains the phthalate DEHP. Phthalates are widely used as plasticizers in medical products and have undergone extensive testing. However, when using the device, it should be taken into consideration that possible health effects when used for long durations in pregnant women, nursing mothers and children cannot be entirely discounted.

Instructions for Disposal:

Take precautions when discarding this device. The device should be disposed in accordance with applicable hospital or national regulations for biologically hazardous waste.

Intended Purpose:

Medline Suction Tubing Family products are intended to be used in various medical and surgical procedures to sample, aspirate or to remove body fluid.

Intended Users :

Intended to be used by healthcare professionals and are not intended to be used outside of the supervision of a clinically trained professional. Intended to be used in healthcare environment, including acute care, long-term acute care, post-acute care, long term care/nursing home, surgical/operating room, and procedural room.

Intended Patient Population:

Intended for use on pediatric and adult patient populations, undergoing a procedure to sample, aspirate, or remove bodily fluids.

***Pediatric:** OR854VCP, ORNEX66VCP
***Adult:** OR853VCA, ORNEX66VCA, ORNEX610VCA

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com

Mandatory action to read instructions for use, Unbedingt Gebrauchsanweisung beachten, Obligation de lire la notice d'utilisation, Verplichte actie om de gebruiksaanwijzing te lezen, Azione obbligatoria: leggere le istruzioni per l'uso, Acción obligatoria de leer las instrucciones de uso, Acção obrigatória para ler as instruções de utilização, Povinné prečítanie si návodu na použitie, Přečtěte si návod k použití, Det är obligatoriskt att läsa bruksanvisningen, Käyttöohjeiden lukeminen on pakollista, Det er påkrævet at læse brugsanvisningerne, Obligatoriske tiltak som må leses før bruk, Η ανάγνωση των οδηγιών είναι υποχρεωτική πριν από τη χρήση, Należy koniecznie przeczytać instrukcję obsługi, Obvezni ukrep je branje navodil za uporabo, Citirea instrucțiunilor de utilizare este obligatorie Задължително е да се прочетат инструкциите за употреба, Kötelező intézkedés a használati utasítás elolvasása, Kullanım talimatlarını okumak zorunludur, يجب قراءة تعليمات الاستخدام إلزاميًا

Not Made with Natural Rubber Latex, Nicht mit Naturkautschuklatex hergestellt, Fabriqué sans latex de caoutchouc naturel, Niet gemaakt met natuurlijke rubberlatex, Non realizzato con lattice di gomma naturale, No fabricado con látex de caucho natural, Feito sem látex de borracha natural, Nie je vyrobené z prírodného kaučukového latexu, Vyrobeno bez použití přírodního kaučuku, Innehåller inte naturgummilatex, Ei ole valmistettu luonnonkumilateksista, Fremstillet uden naturgummilatex, Ikke laget med naturlig gummilatex, Δεν κατασκευάζεται από φυσικό ελαστικό λάτεξ, Nie wyprodukowano z użyciem lateksu kauczuku naturalnego, Ni izdelano iz naravnega kavčukovega lateksa, Nu este fabricat din latex de cauciuc natural, Не е произведено с естествен каучуков латекс, Ei ole valmistatud looduslikust kummilateksist, Nem tartalmaz természetes gumilatexet, Sudėtyje nėra natūralaus kaučiuko latekso, Ne sadrži prirodni gumeni lateks, Doğal kauçuk lateksten yapılmamıştır, غير مصنوع من مطاط اللاتكس الطبيعي

PHT
DEHP

ORNEX + MED-STOP
(ORNEX66VCA - ORNEX66VCP - ORNEX610VCA)

℞ ONLY

Prescription Device Only - For Professional Use Only, Verschreibungspflichtiges Produkt – Nur für den professionellen Gebrauch, Dispositif médical sur ordonnance uniquement - Réservé à un usage professionnel, Apparaat op recept - Uitsluitend voor professioneel gebruik, Dispositivo soggetto a prescrizione medica - Solo per uso professionale, Producto de prescripción médica únicamente - Para uso profesional únicamente, Apenas Dispositivo de Prescrição - Apenas para uso profissional, Len na lekársky predpis – len na profesionálne použitie, Pouze na lékařský předpis – Pouze pro profesionální použití, Endast receptbelagd enhet - Endast för professionellt bruk, Vain reseptillä saatava laite – Vain ammattikäyttöön, Kun receptpligtig enhed – kun til professionel brug, Kun reseptbelagt enhet – Kun for profesjonell bruk, Συσκευή μόνο με ιατρική συνταγή - Μόνο για επαγγελματική χρήση, Wyrób dostępny wyłącznie na receptę — wyłącznie do użytku profesjonalnego, Samo na recept - Samo za profesionalno uporabo, Numai dispozitiv cu prescripție medicală - Numai pentru uz profesional, Устройство само с рецепта - Само за професионална употреба, Ainult retsepti alusel väljastatav seade – ainult professionaalseks kasutamiseks, Csak receptre kapható eszköz - Kizárólag professzionális használatra, Tik receptinis prietaisas – tik profesionaliam naudojimui, Samo uređaj na recept - Samo za profesionalnu uporabu, Reçeteyle satılan cihaz - Sadece profesyonel kullanım içindir, جهاز يُصرف بوصفة طبية فقط - للاستخدام المهني فقط

Manufactured in China for:
Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA.

CE

EC REP Medline International France SAS,
5 rue Charles Lindbergh, 44110 Châteaubriant, France

CH REP **CH rep and importer:** Medline International Switzerland SARL,
c/o MN & Associés SA, 1 Place de Longemalle, 1204 Genève, Switzerland

UK CA **UK representative and importer in UK:**
Medline Industries Ltd,
WA4 6HL,UK

Medline International B.V.,
Catharijnesingel 47, 3511 GC
Utrecht, The Netherlands

RG26SJP 2026-07

Medline International France SAS
Immeuble Australia • 19 rue Stephenson
Montigny-le-Bretonneux • 78180 • France
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel : +33 (0)2 44 05 30 67
Tel : +33 (0)2 44 05 30 68
GMB-EU-FSN-FSCA-CHBT@medline.com