

I.V. Securement Dressings

3M[™] Tegaderm[™] CHG Chlorhexidine Gluconate I.V. Securement Dressing FAQ

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Antimicrobial efficacy

Question	Answer
Is 3M [™] Tegaderm [™] CHG Dressing cleared by the regulatory authorities for catheter-related bloodstream infection (CRBSI) reduction? How is it classified according to EU Medical Device Directive?	3M [™] Tegaderm [™] CHG Dressing is the only transparent securement dressing proven to reduce CRBSI and vascular catheter colonization that aligns with evidence-based guidelines and practice standards. 3M received CE mark on expanded claims in 2014 and cleared by FDA in U.S. in 2017. Tegaderm CHG Dressing has been shown to reduce the incidence of CRBSI and catheter colonisation in a large, randomised, controlled clinical trial for both short-term central venous (CVC) and arterial catheters. ¹ According to Medical device directive 93/42/EEC Tegaderm CHG Dressing is classified in EU as medical device Class III.
Has 3M [™] Tegaderm [™] CHG Dressing been studied to reduce catheter-related bloodstream infections (CRBSI) in multiple randomised studies?	3M [™] Tegaderm [™] CHG Dressing has multiple randomised controlled trials (RCT). In addition to the Timsit 2012 RCT for short-term central venous (CVC) and arterial catheters, ¹ there is an RCT on dialysis patients ² and another on a neutropenic patient population. ³ Additionally, there are two meta-analyses that include Tegaderm CHG Dressing. ^{4,5} A meta-analysis is the highest level of clinical evidence, referencing multiple RCTs.
	Review the full 3M [™] Tegaderm [™] CHG Dressing clinical evidence summary.
How does a CHG gel pad provide antimicrobial protection? Does it provide 360-degree protection?	CHG is an active antimicrobial component of the 3M [™] Tegaderm [™] CHG Dressing gel pad. The gel is composed of water, 2% chlorhexidine gluconate and other polymers. The aqueous nature of the gel pad and CHG allows for immediate antimicrobial action upon application to skin. In four clinical studies, the CHG gel pad has been shown to provide complete antimicrobial protection on and under a vascular catheter segment. ^{6,7,8,9} According to two published studies, Tegaderm CHG Dressing provides better antimicrobial protection compared to BIOPATCH [®] Disks. ^{10,11}
Does 3M [™] Tegaderm [™] CHG Dressing provide coverage around suture sites?	Current international guidelines recognise sutures as potential sources of infection and central venous catheter (CVC) complications. ¹² 3M [™] Tegaderm [™] CHG Dressing is effective where the CHG gel pad is in contact with the skin and its surrounding inhibition zone. According to one study, Tegaderm CHG Dressing reduces the number of microorganisms at the insertion site, suture site, sutures and catheter surface. ⁷ Note: Tegaderm CHG Dressing is not indicated to reduce bacterial colonisation of sutures and suture sites. No clinical correlations are intended with in vitro testing.
Does 25% weight/weight CHG provide better antisepsis than 2% weight/weight CHG?	According to international guidelines, segments regarding the pathogenesis of a catheter-related bloodstream infection (CRBSI), migration of skin micro-organisms at the insertion site is considered as a major contamination route. ^{12,20,22} 3M [™] Tegaderm [™] CHG Dressing has been demonstrated to be as effective, or better at reducing skin flora on healthy subjects than BIOPATCH [®] Disks. ^{10,11} Tegaderm CHG Dressing has a concentration of 2% CHG weight by weight and does not require additional moisture for activation.

Product features and specifications

Question	Answer	
What is the difference between 3M [™] Tegaderm [™] CHG Dressing and BIOPATCH [®] Disks?	3M [™] Tegaderm [™] CHG Dressing is the only transparent securement dressing proven to reduce catheter-related bloodstream infections (CRBSI) and vascular catheter colonization that aligns with evidence-based guidelines and practice standards. The dressing provides four essential elements you need to protect IV sites in one integrated, easy-to-use product including infection reduction, site visibility, consistent application and catheter securement.	
	3M [™] Tegaderm [™] CHG Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices. Tegaderm CHG Dressing is intended to reduce skin colonisation and catheter colonisation and to suppress regrowth of microorganisms commonly related to bloodstream infections. Tegaderm CHG is intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	
	For more information, visit engage.3M.com/chgcomparison.	
Does the 3M [™] Tegaderm [™] CHG Dressing gel pad absorb fluid, such as drainage or blood?	Yes. 3M [™] Tegaderm [™] CHG Dressing absorbs blood, sweat and exudates (8x its weight in saline and 3x its weight in blood) and still maintains antimicrobial effectiveness. As the gel pad absorbs fluid, it swells and becomes larger in size. Drainage should remain contained within the gel pad without obscuring visualisation of the catheter insertion site. Apply an external gauze pressure dressing with tape to help reduce drainage on newly placed catheters.	
	According to 2014 Epic3 National Evidence Based Guidelines: IVAD19, use a sterile gauze dressing if a patient has profuse perspiration or if the insertion site is bleeding or leaking, and change when inspection of the insertion site is necessary or when the dressing becomes damp, loosened or soiled. Replace with a transparent semi-permeable dressing as soon as possible. Class D/GPP 20. ²⁰ Tegaderm CHG Dressing is not intended to be used on sites which are actively oozing or bleeding, or large amounts of moisture or drainage. Tegaderm CHG Dressing has not been tested in combination with hemostatic agents or skin adhesives regarding safety and efficacy.	
Is the 3M [™] Tegaderm [™] CHG Dressing adhesive pressure sensitive?	Yes, firm pressure should be applied to the entire dressing surface, before and after removal of the paper frame to enhance adhesion.	
Does the 3M [™] Tegaderm [™] CHG Dressing meet the current international requirement of a transparent semi-permeable membrane? Is it a breathable dressing?	3M [™] Tegaderm [™] CHG Dressing consists of a gel pad containing CHG integrated with a Tegaderm Transparent Film Dressing. Moisture readily passes through the gel to the dressing film to be released as vapour. The pattern-coated adhesive technology enhances the ability of moisture vapour transfer. The Tegaderm Film acts as a selective filter, providing a barrier to external liquids, bacteria, and viruses* while allowing water vapour, oxygen, and carbon dioxide to be easily exchanged.	
	* <i>In vitro</i> testing shows that the film provides a barrier against viruses 27 nm in diameter or larger while the dressing remains intact without leakage.	

Product features and specifications continued

Question	Answer	
Does 3M [™] Tegaderm [™] CHG Dressing meet the definition of an engineered stabilisation device (ESD)?	Yes, 3M™ Tegaderm™ CHG Dressing meets the definition of an ESD, as reflected in the 2016 updates to the Infusion Nurses Society (INS) Standards of Practice. ¹³ Refer to securement features below.	
When was 3M [™] Tegaderm [™] CHG Dressing originally launched for sale? Have there been any changes or improvements?	As a leader in innovation, 3M is continuously im customer insights. 3M [™] Tegaderm [™] CHG Dressi in 2008. The breathability of the dressing was ir in 2016 with improved breathability, conformabi 3M introduced a product enhancement specific Dressing 1657R to help conform around large-bo This design upgrade introduces perforations on securement tape strip as pictured below.	ng was first launched for sale nproved in 2010. It was again redesigned ility, notches and tape strips. In 2019, to Tegaderm CHG I.V. Securement pre catheters and aid with removal.
Large securement tape strip with notch Promotes consistent application and enhances stabilization. Perforations on the tape strip can be opened to aid with dressing removal.*	Conforming edge border Uses technology designed to reduce edge-lift.	Achiorhexidine gluconate (CHG) gel pad provides antimicrobial protection for up to 7 days.
	Conforming keyhole notch A notch allows catheter lumens to fit better and stay in place. Perforations allow keyhole notch to conform around large catheters.*	A waterproof, sterile barrier protects against external contaminants ^{**} Highly breathable transparent film.

*Perforations apply to Tegaderm[™] CHG Dressing 1657R only.

**In vitro testing shows that the film provides a barrier against viruses 27 nm in diameter or larger while the dressing remains intact without leakage.

Application and removal

Question	Answer	
Can 3M [™] Tegaderm [™] CHG Dressing be used for peripheral IVs (PIV)?	Yes. There are studies suggesting that PIVs in place for 3–4 days or longer can be a significant source of contamination from skin flora responsible for catheter-related bloodstream infections (CRBSI). ^{14,15,16,17}	
When do I need to change the 3M [™] Tegaderm [™] CHG Dressing?	In accordance with international guidelines, transparent adhesive dressings for central venous catheters (CVC), including peripherally inserted central catheters (PICC), should be changed when the integrity of the dressing is compromised, soiled, moist or loosened or at least weekly for adults. ^{12,20,21,22} Indications to change the dressing include:	
	If the dressing becomes loose, soiled or compromised in any way	
	If the site is obscured or no longer visible	
	If there is visible drainage outside the gel pad	
	If the dressing appears to be saturated or overly swollen*	
	*Note: To test if the dressing is fully saturated, lightly press down on a corner of the gel pad with your finger. If the gel pad remains displaced once your finger is removed, the dressing should be changed. 3M [™] Tegaderm [™] CHG Dressing gel pad is not intended to be used to absorb large quantities of blood or fluid.	
What is the best way to remove 3M™ Tegaderm™ CHG Dressing?	Minimise catheter movement during dressing changes. Remove appropriate tape strips first. Slowly peel the dressing following the catheter from where it exits the dressing toward the insertion site using the 'low and slow' removal method. To prevent gel pad from separating from dressing, grasp a corner of the gel pad and the transparent film between thumb and finger, then apply a sterile fluid (e.g. saline, alcohol pad or antiseptic swab) between skin and gel pad to help facilitate removal from skin and catheter.	
	To access all 3M [™] Tegaderm [™] CHG Dressing application and removal videos and resources, visit www.3M.co.uk/vascularaccess	
Can 3M [™] Tegaderm [™] CHG Dressing be left on for 10 days?	3M [™] Tegaderm [™] CHG Dressing has been shown to effectively inhibit re-growth of skir flora on healthy subjects for up to 10 days. ^{6,11} However, consistent with the internationa guidelines, the dressing may remain in place up to 7 days and than be changed. ^{12,13,20,21,2}	

Application and removal continued

Question Answer	
Can a skin antiseptic be used with 3M [™] Tegaderm [™] CHG Dressing?	Yes. According to international guidelines, disinfect clean skin with an appropriate antiseptic before catheter insertion and during dressing changes. ^{12,20} A \geq 0.5% chlorhexidine-based preparation with alcohol is preferred. 3M ^T Tegaderm ^T CHG Dressing is designed to work with 3M ^T Cavilon ^T No Sting Barrier Film, alcohol, povidone iodine, CHG prep with alcohol and sterile saline. Use of Tegaderm CHG Dressing has been demonstrated to reduce skin flora counts on healthy subjects to lower levels than can be achieved with skin preps alone. ^{10,11} In addition, antimicrobial protection will be provided continuously at the site for up to 10 days with Tegaderm CHG Dressing, ⁶ whereas microbes can triple in volume as quickly as 24 hours following skin antisepsis using a standard dressing treated with a CHG prep. ¹⁸ However, consistent with current international guidelines, the dressings should be changed at least weekly for adult patients. ^{12,20,21,22}
After application of a skin antiseptic, how long should the site be allowed to dry before application of the 3M [™] Tegaderm [™] CHG Dressing to avoid skin irritation and edge-lift?	Refer to the Tegaderm CHG Dressing <u>Instructions for use</u> . Let all skin preps dry completely before applying any dressing.
What should I do if I see skin maceration or moisture-related irritation under the 3M™ Tegaderm™ CHG Dressing gel pad?	According to a recent 11-year, real-world study, skin reaction rates for CHG gel and CHG sponge were equivalent at 0.3/1000 catheter days. ¹⁹ Excessive moisture results from sweat, blood/drainage or showering/bathing. 3M [™] Tegaderm [™] CHG Dressing is not intended to absorb a large amount of drainage or fluid. To prevent moisture-related skin issues, clinicians should monitor the CHG gel pad for oversaturation. If maceration is observed, remove the dressing, allow the site to dry completely, apply a gauze and tape dressing per current international guidelines. ¹² The maceration may resolve within a day or so. Once resolved, transition the patient back to a Tegaderm CHG Dressing.

Patient populations and procedures

Question Answer		
Can 3M [™] Tegaderm [™] CHG Dressing be used on infants?	Do not use 3M [™] Tegaderm [™] CHG Dressing on premature infants or infants younger than two months of age. Use of this product on premature infants may result in hypersensitivity reactions or necrosis of the skin. The safety and effectiveness of Tegaderm CHG Dressing has not been established in children under 18 years of age. For full prescribing information, see the Instructions for Use (IFU) . Rx Only.	
Can 3M [™] Tegaderm [™] CHG Dressing be used in BMT/Oncology?	Yes. 3M [™] Tegaderm [™] CHG Dressing has been used successfully in BMT/Oncology since product launch. This patient population is immunocompromised and has fragile, more permeable skin. Monitor the CHG gel pad for oversaturation and moisture to prevent skin maceration. Be sure to stress the importance of allowing the preps to dry before applying the dressing to avoid skin irritation or other complications.	
Can 3M [™] Tegaderm [™] CHG Dressing be used during radiation therapy?	3M™ Tegaderm™ CHG Dressing has not been tested for use during radiation therapy.	
Can I use 3M [™] Tegaderm [™] CHG Dressing on diaphoretic patients?	Yes, 3M [™] Tegaderm [™] CHG Dressing is designed to absorb fluid, however it is not intended to absorb large quantities of fluid. Tegaderm CHG Dressing maintains antimicrobial effectiveness in the presence of perspiration and other fluids and prevents regrowth of skin flora. See question ' <u>When do I need to change the Tegaderm[™] CHG Dressing</u> ?' for more information.	
Can 3M [™] Tegaderm [™] CHG Dressing be used to treat a site infection?	3M [™] Tegaderm [™] CHG Dressing is not indicated for treatment of a suspected or known site infection.	
Can 3M [™] Tegaderm [™] CHG Dressing be used to treat a wound?	No. 3M [™] Tegaderm [™] CHG Dressing should only be applied to skin which is clean, dry and intact. Tissue damage or necrosis may result if applied to non-intact skin.	

Compatibility

Answer	
3M [™] Tegaderm [™] CHG Dressing is cleared for use on percutaneous medical devices that would benefit from microbial reduction. Devices at risk for microbial contamination that could benefit from Tegaderm CHG Dressing include, but are not limited to, intravenous, arterial, epidural, extracorporeal membrane oxygenation (ECMO), implanted ports, surgical drains, cardiac wires (LVADs), subcutaneous therapies, and dialysis catheters. Tegaderm CHG Dressing is designed for skin applications and not mucosal use.	
3M [™] Tegaderm [™] CHG Dressing may be used with a StatLock [®] stabilisation device. Ensure that the gel pad does not overlap onto the plastic wings of the securement device. For device removal, refer to StatLock [®] stabilisation device instructions for use.	
Yes. 3M [™] Cavilon [™] No Sting Barrier Film is compatible with 3M [™] Tegaderm [™] CHG Dressing and can be used to reduce the risk of adhesive trauma. Apply Cavilon No Sting Barrier Film to the area where the dressing will be applied, avoiding the catheter insertion site (2 cm) and where the CHG gel pad will be placed. Cavilon No Sting Barrier Film wand applicators (3343 or 3345) are recommended for IV sites; Cavilon No Sting Barrier Film in spray form (3346) should not be used for IV sites.	
Yes (3M data on file. EM-05-012899).	
Yes (3M data on file. EM-05-012965).	

3M[™] Tegaderm[™] CHG I.V. Securement Dressing instructions for use

1657R, 1658R, 1659R, 1660R

Description

3M[™] Tegaderm[™] CHG Chlorhexidine Gluconate I.V. Securement Dressing is used to cover and protect catheter sites and to secure devices to skin. It is available in a variety of shapes and sizes.

Tegaderm CHG dressing consists of a transparent adhesive dressing and an integrated gel pad containing 2% w/w chlorhexidine gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity. The gel pad absorbs fluid. The transparent film provides an effective barrier against external contamination including fluids (waterproof), bacteria, viruses* and yeast, and protects the I.V. site.

In vitro testing (time kill and zone of inhibition) demonstrates that the Tegaderm CHG gel pad in the dressing has an antimicrobial effect against a variety of gram-positive and gram-negative bacteria, and yeast.

Tegaderm CHG dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapour exchange.

*In vitro testing shows that the transparent film of the Tegaderm[™] CHG dressing provides a viral barrier from viruses 27 nm in diameter or larger while the dressing remains intact without leakage. The barrier to viruses is due to the physical properties of the dressing, rather than the ancillary properties of CHG.

Indications

Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include central venous and arterial catheters, other intravascular catheters and percutaneous devices. Tegaderm CHG Dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to bloodstream infections. Tegaderm CHG is intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

Warnings

Do not use Tegaderm CHG dressings on premature infants or infants younger than 2 months of age. Use of this product on premature infants may result in hypersensitivity reactions or necrosis of the skin.

The safety and effectiveness of Tegaderm CHG dressings has not been evaluated in children under 18 years of age. For external use only. Do not allow this product to contact ears, eyes, mouth or mucous membranes. Do not use this product on patients with known hypersensitivity to chlorhexidine gluconate.

The use of chlorhexidine gluconate containing products has been reported to cause irritations, sensitisation, and generalised allergic reactions. If allergic reactions occur, discontinue use immediatly, and if severe, contact a physician.

Hypersensitivity reactions associated with topical use of chlorhexidine gluconate have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing chlorhexidine gluconate, which were used during urinary tract procedures. Caution should be used when using chlorhexidine gluconate containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.

Precautions

Tegaderm CHG dressing should not be placed over infected wounds. It is not intended to be used as a treatment of percutaneous device-related infections.

In the case of clinical wound infection, systemic antibacterials should be used if indicated.

Any active bleeding at the insertion site should be stabilised before applying the dressing.

Do not stretch the dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Do not reuse. Reuse may result in compromising product integrity and lead to device failure.

Clinical trial results: a randomised, controlled clinical trial consisting of 1879 subjects with 4163 central venous and arterial catheter insertion sites was conducted at 11 hospitals.¹ Results showed that the use of Tegaderm CHG resulted in a statistically significant 60% reduction in the incidence of catheter-related bloodstream infections (P=0.02). Study results also demonstrate a statistically significant reduction in skin colonization (P<0.001) and catheter colonization (P<0.0001) in the chlorhexidine vs. non-chlorhexidine group.

Variable	Non-chlorhexidine vs. chlorhexidine dressings (941 patients/2055 catheters vs. 938 patients/2108 catheters)
Catheter-related bloodstrea	am infection
Incidence densities (n per 1000 catheter-days)	1.3 vs. 0.5
Hazard ratio	0.402 [0.186 to 0.868], P=0.02
Catheter colonization	
Incidence densities (n per 1000 catheter-days)	10.9 vs. 4.3
Hazard ratio	0.412 [0.306 to 0.556], P<0.0001

 Timsit JF et al Randomised Controlled Trial of Chlorhexidine Dressing and Highly Adhesive Dressing for Preventing Catheter-Related Infections in Critically III Adults Am. J. Respir. Crit. Care Med. 2012; 186:1272–1278

Instructions for use

Failure to follow the manufacturer's instructions for use may result in complications including skin irritation and/or maceration.

Dressing selection: choose a dressing large enough to provide at least one inch margin of adherence on dry, healthy skin around the catheter site.

Site preparation: prepare the site according to institution protocol. Clipping of hair at the site may improve dressing adhesion. Shaving is not recommended. The skin should be clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion. Any active bleeding at the insertion site should be stabilised before applying the dressing.

3M[™] Tegaderm[™] CHG I.V. Securement Dressing

instructions for use continued

1657R, 1658R, 1659R, 1660R

Application

- 1 Open package and remove sterile dressing.
- 2 Peel liner from dressing, exposing adhesive surface.
- 3 Avoid stretching the dressing during application to reduce the risk of mechanical skin trauma.
- 4 Centre the gel pad over the catheter insertion site. Apply firm pressure to entire dressing starting in the centre to the outer frame edges to enhance adhesion.
- 5 Slowly remove frame while smoothing down transparent film dressing edges.
- 6 Smooth the transparent film dressing from the center towards the dressing edges, using firm pressure to enhance adhesion.
- 7 After dressing has been applied, apply the sterile tape strip(s) to further secure I.V. tubing or to stabilise catheter. Refer to figures on packaging.
- 8 Document dressing change information on label according to facility protocol. Remove label from frame and place on dressing.

Site care

- 1 The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.
- 2 Inspect the dressing daily and change the dressing as necessary, in accordance with facility protocol; dressing changes should occur at a minimum of every 7 days, per current Centers for Disease Control and Prevention (CDC) recommendations. Dressing changes may be needed more frequently with highly exudative sites.

The Tegaderm CHG dressing should be changed as necessary:

- If the dressing becomes loose, soiled or compromised in any way
- If the site is obscured or no longer visible
- If there is visible drainage outside the gel pad
- ► If the dressing appears to be saturated or overly swollen
- To test if the dressing is fully saturated, lightly press down on a corner of the gel pad with your finger. If the gel pad remains displaced once your finger is removed, the dressing should be changed

Note: Tegaderm CHG dressing is not designed to absorb large quantities of blood or fluid.

Removal

Stabilise catheter during removal of the Tegaderm CHG dressing.

- 1 Remove documentation label and securement tape strip(s) from top of dressing.
- 2 Using a low and slow removal technique, start removing the dressing from where the catheter or tubing exits the dressing toward the catheter insertion site. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin.

- 3 When the CHG gel pad is exposed, grasp a corner of the gel pad and the transparent film dressing between thumb and finger.
- 4 Apply sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) between gel pad and skin to facilitate removal of the gel pad dressing. If needed, a medical adhesive solvent can be used to help remove the dressing border.
- 5 Continue the low and slow removal method until the dressing is completely removed.

Shelf life and storage information

For best results, store in a cool, dry place. For shelf life, refer to the expiration date on the package.

Sterility of the dressing is guaranteed unless individual package is damaged or open.

For further information contact your local 3M representative or contact us at www.3M.com and select your country.

Catalogue number	Dressing size	Average amount of CHG per dressing (mg based on gel pad size)
1657R	8.5cm x 11.5cm	45
1658R	10cm x 12cm	45
1659R	10cm x 15.5cm	78
1660R	7cm x 8.5cm	15

Explanation of symbols



Not made with natural rubber latex



Caution, see instructions for use



Do not use if package is damaged or open



Do not reuse



Use by date

LOT Batch co





Manufacturer



Do not re-sterilise

Sterilised using ethylene oxide



Important safety information for 3M[™] Tegaderm[™] CHG Dressing

Do not use Tegaderm CHG Dressing on premature infants or infants younger than two months of age. Use of this product on premature infants may result in hypersensitivity reactions or necrosis of the skin. The safety and effectiveness of Tegaderm CHG Dressing has not been established in children under 18 years of age. For full prescribing information, see the **Instructions for use (IFU)**.



To learn more about 3M[™] Tegaderm[™] CHG Dressings, visit us at www.3M.co.uk/vascularaccess, contact your 3M Medical Solutions representative or call the 3M customer helpline at 0330 053 8938.

References

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