

3M

Tegaderm™

CHG Chlorhexidine Gluconate
I.V. Securement Dressing

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

Contents

Antimicrobial Efficacy

- Pg. 3** Is Tegaderm™ CHG Dressing cleared by the U.S. Food and Drug Administration (FDA) for catheter-related bloodstream infection (CRBSI) reduction?
- Pg. 3** Has Tegaderm™ CHG Dressing been studied to reduce catheter-related bloodstream infections (CRBSI) in multiple randomized studies?
- Pg. 3** How does a CHG gel pad provide antimicrobial protection? Does it provide 360-degree protection?
- Pg. 3** Does Tegaderm™ CHG Dressing provide coverage around suture sites?
- Pg. 3** Does 25% weight/weight CHG provide better antisepsis than 2% weight/weight CHG?

Product Features and Specifications

- Pg. 4** What is the difference between Tegaderm™ CHG Dressing and BIOPATCH® Disks?
- Pg. 4** Does the Tegaderm™ CHG Dressing gel pad absorb fluid, such as drainage or blood?
- Pg. 4** Is the Tegaderm™ CHG Dressing adhesive pressure sensitive?
- Pg. 4** Does the Tegaderm™ CHG Dressing meet the Centers for Disease Control and Prevention (CDC) requirement of a transparent semipermeable membrane? Is it a breathable dressing?
- Pg. 5** Does Tegaderm™ CHG Dressing meet the definition of an engineered stabilization device (ESD)?
- Pg. 5** When was Tegaderm™ CHG Dressing originally launched for sale? Have there been any changes or improvements?

Application and Removal

- Pg. 6** Can Tegaderm™ CHG Dressing be used for peripheral IVs (PIV)?
- Pg. 6** When do I need to change the Tegaderm™ CHG Dressing?
- Pg. 6** What is the best way to remove Tegaderm™ CHG Dressing?
- Pg. 6** Can Tegaderm™ CHG Dressing be left on for 10 days?

Application and Removal (cont.)

- Pg. 7** Can a skin antiseptic be used with Tegaderm™ CHG Dressing?
- Pg. 7** After application of a skin antiseptic, how long should the site be allowed to dry before application of the Tegaderm™ CHG Dressing to avoid skin irritation and edge-lift?
- Pg. 7** What should I do if I see skin maceration or moisture-related irritation under the Tegaderm™ CHG Dressing gel pad?

Patient Populations and Procedures

- Pg. 8** Can Tegaderm™ CHG Dressing be used on infants?
- Pg. 8** Can Tegaderm™ CHG Dressing be used in BMT/Oncology?
- Pg. 8** Can Tegaderm™ CHG Dressing be used during radiation therapy?
- Pg. 8** Can I use Tegaderm™ CHG Dressing on diaphoretic patients?
- Pg. 8** Can Tegaderm™ CHG Dressing be used to treat a site infection?
- Pg. 8** Can Tegaderm™ CHG Dressing be used to treat a wound?

Compatibility

- Pg. 9** What other devices can Tegaderm™ CHG Dressing be used with?
- Pg. 9** Does Tegaderm™ CHG Dressing fit with a StatLock® PICC Plus Stabilization Device?
- Pg. 9** Can I use Tegaderm™ CHG Dressing together with 3M™ Cavilon™ No Sting Barrier Film?
- Pg. 9** Is Tegaderm™ CHG Dressing MRI compatible?
- Pg. 9** Can Tegaderm™ CHG Dressing be used in a hyperbaric chamber?

Antimicrobial Efficacy

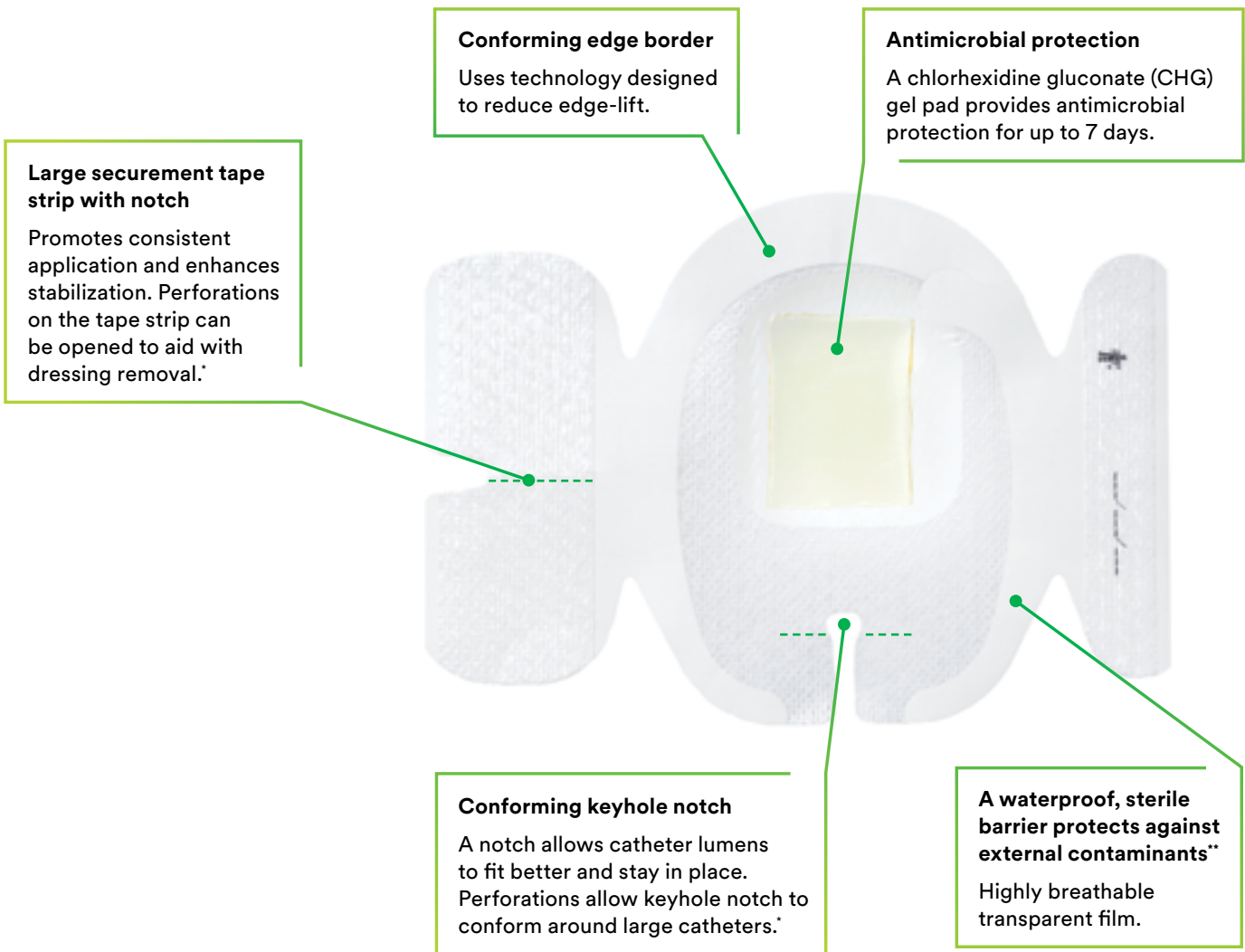
| QUESTION | ANSWER |
|---|--|
| Is Tegaderm™ CHG Dressing cleared by the U.S. Food and Drug Administration (FDA) for catheter-related bloodstream infection (CRBSI) reduction? | Tegaderm™ CHG Dressing is the only transparent securement dressing proven to reduce CRBSI and vascular catheter colonization that aligns with evidence-based guidelines and practice standards. 3M received expanded claims from the FDA in May 2017. Tegaderm™ CHG Dressing has been shown to reduce the incidence of CRBSI and catheter colonization in a large, randomized, controlled clinical trial for both short-term central venous (CVC) and arterial catheters. ¹ |
| Has Tegaderm™ CHG Dressing been studied to reduce catheter-related bloodstream infections (CRBSI) in multiple randomized studies? | Tegaderm™ CHG Dressing has multiple randomized 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. <u>Review the full Tegaderm™ CHG Dressing clinical evidence summary.</u> |
| How does a CHG gel pad provide antimicrobial protection? Does it provide 360-degree protection? | CHG is an active antimicrobial component of the 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 Tegaderm™ CHG Dressing provide coverage around suture sites? | The 2011 Centers for Disease Control and Prevention (CDC) Guidelines recognize sutures as potential sources of infection and central venous catheter (CVC) complications. ¹² 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 <i>Note: Tegaderm™ CHG Dressing is not indicated to reduce bacterial colonization of sutures and suture sites. No clinical correlations are intended with in vitro testing.</i> |
| Does 25% weight/weight CHG provide better antisepsis than 2% weight/weight CHG? | According to the 2011 CDC Guidelines segment regarding the pathogenesis of a catheter-related bloodstream infection (CRBSI), the most common route is migration of skin organisms at the insertion site. ¹² 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 Tegaderm™ CHG Dressing and BIOPATCH® Disks? | <p>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.</p> <p>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.</p> <p>The Tegaderm™ CHG Dressing continues to be substantially equivalent to the BIOPATCH® Disk. As part of the substantial equivalence determination, the U.S. Food and Drug Administration (FDA) has acknowledged that there are minor differences in technological characteristics between the two products, but that these differences do not affect the safety and effectiveness of the device when used as labeled.</p> <p>For more information, visit engage.3m.com/chgcomparison.</p> |
| Does the Tegaderm™ CHG Dressing gel pad absorb fluid, such as drainage or blood? | <p>Yes. 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 visualization of the catheter insertion site. Apply an external gauze pressure dressing with tape to help reduce drainage on newly placed catheters.</p> <p>According to the 2011 Centers for Disease Control and Prevention (CDC) Guidelines: If the patient is diaphoretic or if the site is bleeding or oozing, use a gauze dressing until this is resolved (Category II). Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled (Category IB).¹² 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.</p> |
| Is the Tegaderm™ CHG Dressing adhesive pressure sensitive? | <p>Yes, firm pressure should be applied to the entire dressing surface, before and after removal of the paper frame to enhance adhesion.</p> |
| Does the Tegaderm™ CHG Dressing meet the Centers for Disease Control and Prevention (CDC) requirement of a transparent semipermeable membrane? Is it a breathable dressing? | <p>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 vapor. The pattern-coated adhesive technology enhances the ability of moisture vapor transfer. The Tegaderm™ Film acts as a selective filter, providing a barrier to external liquids, bacteria, and viruses* while allowing water vapor, oxygen, and carbon dioxide to be easily exchanged.</p> <p><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.</p> |

Product Features and Specifications (cont.)

| QUESTION | ANSWER |
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| <p>Does Tegaderm™ CHG Dressing meet the definition of an engineered stabilization device (ESD)?</p> | <p>Yes, 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.</p> |
| <p>When was Tegaderm™ CHG Dressing originally launched for sale? Have there been any changes or improvements?</p> | <p>As a leader in innovation, 3M is continuously improving our products based on science and customer insights. Tegaderm™ CHG Dressing was first launched for sale in 2008. The breathability of the dressing was improved in 2010. It was again redesigned in 2016 with improved breathability, conformability, notches and tape strips. In 2019, 3M introduced a product enhancement specific to 3M™ Tegaderm™ CHG I.V. Securement Dressing 1657 to help conform around large-bore catheters and aid with removal. This design upgrade introduces perforations on the keyhole notch and on the securement tape strip as pictured below.</p> |



*Perforations apply to Tegaderm™ CHG Dressing 1657 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 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 Tegaderm™ CHG Dressing? | <p>In accordance with 2011 Centers for Disease Control and Prevention (CDC) 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 Indications to change the dressing include:</p> <ul style="list-style-type: none">• 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* <p>*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. Tegaderm™ CHG Dressing gel pad is not intended to be used to absorb large quantities of blood or fluid.</p> |
| What is the best way to remove Tegaderm™ CHG Dressing? | <p>Minimize 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.</p> <p>To access all Tegaderm™ CHG Dressing application and removal videos and resources, visit 3M.com/IVtraining.</p> |
| Can Tegaderm™ CHG Dressing be left on for 10 days? | Tegaderm™ CHG Dressing has been shown to effectively inhibit re-growth of skin flora on healthy subjects for up to 10 days. ^{6,11} However, consistent with the 2011 Centers for Disease Control and Prevention (CDC) Guidelines and the 2016 updates to the Infusion Nurses Society (INS) Infusion Therapy Standards of Practice, the dressing may remain in place up to 7 days and then be changed. ^{12,13} |

Application and Removal (cont.)

| QUESTION | ANSWER |
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| Can a skin antiseptic be used with Tegaderm™ CHG Dressing? | Yes. According to the 2011 Centers for Disease Control and Prevention (CDC) Guidelines, disinfect clean skin with an appropriate antiseptic before catheter insertion and during dressing changes. ¹² A ≥ 0.5% chlorhexidine-based preparation with alcohol is preferred. Tegaderm™ CHG Dressing is designed to work with 3M™ Cavilon™ 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 CDC 2011 Guidelines, the dressings should be changed “at least weekly for adult patients, depending on the circumstances of the individual patient.” ¹² |
| After application of a skin antiseptic, how long should the site be allowed to dry before application of the Tegaderm™ CHG Dressing to avoid skin irritation and edge-lift? | Refer to the Tegaderm™ CHG Dressing Instructions for Use . 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 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. 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 the 2011 Centers for Disease Control and Prevention (CDC) 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 Tegaderm™ CHG Dressing be used on infants? | 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 <u>Instructions for Use (IFU)</u> . Rx Only. |
| Can Tegaderm™ CHG Dressing be used in BMT/Oncology? | Yes. 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 Tegaderm™ CHG Dressing be used during radiation therapy? | Tegaderm™ CHG Dressing has not been tested for use during radiation therapy. |
| Can I use Tegaderm™ CHG Dressing on diaphoretic patients? | Yes, 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 Tegaderm™ CHG Dressing be used to treat a site infection? | Tegaderm™ CHG Dressing is not indicated for treatment of a suspected or known site infection. |
| Can Tegaderm™ CHG Dressing be used to treat a wound? | No. 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

| QUESTION | ANSWER |
|---|--|
| What other devices can Tegaderm™ CHG Dressing be used with? | 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. |
| Does Tegaderm™ CHG Dressing fit with a StatLock® PICC Plus Stabilization Device? | Tegaderm™ CHG Dressing may be used with a StatLock® stabilization device. Ensure that the gel pad does not overlap onto the plastic wings of the securement device. For device removal, refer to StatLock® stabilization device instructions for use. |
| Can I use Tegaderm™ CHG Dressing together with 3M™ Cavilon™ No Sting Barrier Film? | Yes. Cavilon™ No Sting Barrier Film is compatible with 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. |
| Is Tegaderm™ CHG Dressing MRI compatible? | Yes (3M data on file. EM-05-012899). |
| Can Tegaderm™ CHG Dressing be used in a hyperbaric chamber? | Yes (3M data on file. EM-05-012965). |

Important Safety Information for 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)**. Rx Only.

Additional Resources



3M.com/IVtraining



[3M Health Care YouTube Channel](#)



[HealthStream® Training Modules](#)

For More Information

Visit 3M.com/TegadermCHG, review Tegaderm™ CHG Dressings **Instructions for Use**, contact your 3M Medical Solutions representative, or call the 3M Health Care Customer Helpline at **1-800-228-3957**. Outside of the United States, contact your local 3M subsidiary.

To access all Tegaderm™ CHG Dressing application and removal videos and resources, visit 3M.com/IVtraining.

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Medical Solutions Division

3M Health Care
2510 Conway Avenue
St. Paul, MN 55144 USA

Phone 1-800-228-3957
Web 3M.com/Medical

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