„3M™ Tegaderm™ CHG“ chlorheksidino gliukonato I.V. tvarsčiai

1 p.d.

Kam rizikuoti dėl kraujo infekcijų?

Įrodyta ir indikuota, kad „Tegaderm CHG“ tvarstis mažina su kateteriais susijusių kraujo infekcijų (CRBSI) bei kolonizacijos ties kateteriu riziką. Tokia indikacija yra tik skaidriam I. V. tvarsčiui.

- Kliniškai įrodyta, kad centrinės venos ir (arba) arterijos kateterius turintiems pacientams, CRBSI rizika sumažėjo 60 proc.[1]
- Kliniškai įrodyta, kad centrinės venos ir (arba) arterijos kateterius turintiems pacientams pagrindinės su kateteriais susijusios infekcijos rizika sumažėja 67 proc.[1]
- Kliniškai įrodyta, kad centrinės venos ir (arba) arterijos kateterius turintiems pacientams, kolonizacijos ties oda ir kateteriu rizika sumažėja 61 proc.[1]
- Iki septynių dienų užtikrina vienodą antimikrobinį poveikį.[2]
- Tvarstį „viskas viename“ lengva naudoti, kaip ir „3M™ Tegaderm™“ I. V. tvarstį.
- Skaidrus, todėl patogu stebėti kateterio įvedimo vietą.

„3M™ Tegaderm™ CHG“ chlorheksidino gliukonato I.V. tvarsčiai

Patikima apsauga, kuria

Su kateterio įvedimu susijusios kraujo infekcijos (CRBSI) yra vienos sunkiausių ir sudėtingiausių su sveikatos priežiūra susijusių infekcijų (HCAI), kurių gydymas brangiai kainuoja, dėl jų reikia ilgiau likti ligoninėje, gali prasidėti ligos ar net ištikti mirtis.

Pramonės, vyriausybių ir klinikų iniciatyvos stipriai sumažino CRBSI riziką, kaštus bei dažnumą, tačiau net ir vieno CRBSI atvejo yra per daug.

Net jei tokių infekcijų pasitaiko retai, CRBSI riziką galite dar labiau sumažinti, naudodami „Tegaderm CHG“ tvarsčius.

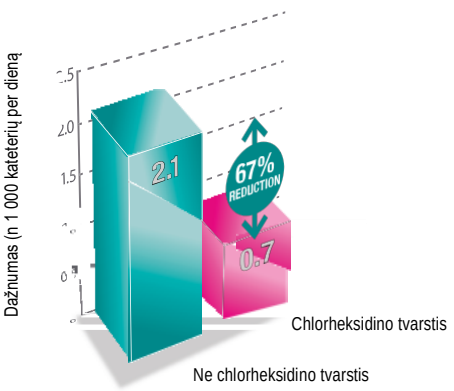
Įrodyta – sumažina su kateterių įvedimu susijusias rizikas

Didžiausiame kada nors atliktame atsitiktiniame kontroliuojamame tyrime (RCT), skirtame įvertinti CHG turinčius gelinius tvarsčius (4 163 kateterių buvo įvesta 1 879 pacientams), nustatyta, kad „Tegaderm CHG“ tvarčiai gerokai sumažina CRBSI riziką, naudojant kartu su kitomis geriausios praktikos intervencijomis[1] (žr. 1 pav.).

- **Indikuota ir kliniškai įrodyta**, kad centrinėje venoje ar arterijoje kateterius turintiems pacientams, pagrindinės su kateteriais susijusios infekcijos (pagrindinės CRI) rizika sumažėja 67 proc.[1] (žr. 2 pav.).
- **Indikuota ir kliniškai įrodyta**, kad centrinės venos ir arterijos kateterius turintiems pacientams, sumažėjo kolonizacijos ties kateteriu rizika (žr. 3 pav.).
- Stebėjimo tyrimuose nustatyta, kad sumažėjo su centrine linija susijusių kraujo infekcijų (CLABSI) atvejų.[3]
- Įrodyta, kad po odos paruošimo[4], tvarstis **iki septynių dienų nuslopina odos floros dauginimąsi** ir efektyviai kovoja su įvairiais klinikiniu požiūriu svarbiais mikroorganizmais[5], įskaitant atsparias atmainas[2].
- Nuo mikrobų septintą dieną saugo taip pat efektyviai, kaip ir pirmą dieną[2].
- Sugeria skysčius (prakaitą, kraują ir išskyras) nepakenkiant antimikrobinėms savybėms[6].
- Įrodytas CHG gelio **antimikrobinis poveikis** sunkiomis eksperimentinėmis sąlygomis, naudojant kateterį ir kraujo baltymus. Tyrimo rezultatai rodo, kad dėl gelio poveikio, CHG kateterį buvo galima įvesti po kateteriu[2].

1 pav. Su kateteriu susijusios kraujo infekcijos

2 pav. Pagrindinės su kateteriu susijusios infekcijos



3 pav. Kolonizacija ties kateteriu

galite pasikliauti

„Viskas viename“ antimikrobinis skaidrus tvarstis – patogus ir saugus

- „3M™ Tegaderm™“ plėvelė suteikia galimybę nuolat stebėti įvedimo vietą.
- „Tegaderm“ plėvelė su 2 proc. chlorheksidino gliukonato gelio pagalvėle atitinka kūno formas ir prisitaiko prie paciento judesių.
- Pusiau peršlampama ir visiškai orui laidi plėvelė leidžia pasišalinti drėgmei.
- CHG nereikia papildomos drėgmės ir jis nuolat veikia, kad apsaugotų.

Išskirtinė apsauga

- Sutvirtinti kraštai ir saugumą garantuojantys grioveliai.
- Minkšti prilimpantys kraštai aplink kateterio įvedimo vietą suformuoja apsauginę zoną.

Suderinama su I. V. vietos geriausiomis priežiūros praktikomis ir protokolais

- Sukuria hermetišką, sterilų barjerą nuo išorinių teršalų, įskaitant skysčius, bakterijas ir virusus*.
- Kaip ir rekomenduoja CDC 1A gairės bei infuzijos praktikos standartai, leidžia nuolat stebėti įvedimo vietą ir matyti, ar neprasidėjo infekcija.[7,8]
- Pagal INS ir CDC apibrėžimą, tvarstis laikomas kateterio tvirtinimo priemone ar stabilizavimo įtaisu.[7,8]
- Atlikus atsitiktinį kontroliuojamą „Tegaderm CHG“ tvarsčio tyrimą nustatyta, kad jis atitinka „Epic[3]“ rekomendaciją dėl chlorheksidinu impregnuotų tvarsčių naudojimo su centrinės venos kateteriais.[9]

Literatūra

1. Timsit JF, et al. Randomized Controlled Trial of Chlorhexidine Dressing and Highly Adhesive Dressing for Preventing Catheter-Related Infections in critically ill adults. American Journal of Respiratory and Critical Care Medicine 2012; 186 (12):1272-1278.
2. Karpanen TJ, et al. (2011) Antimicrobial activity of a Chlorhexidine intravascular catheter site gel dressing, Journal of Antimicrobial Chemotherapy, 66: 1777-1784.
3 Scheithauer S, Lewalter K, Schröder J, Koch A, Häfner H, Krizanovic V, Nowicki K, Hilgers RD, Lemmen SW. Reduction of central venous line-associated bloodstream infection rates by using a chlorhexidine-containing dressing.
4 Bashir MH, et al. (2012) Suppression of regrowth of normal skin flora under chlorhexidine gluconate dressings applied to chlorhexidinegluconate-prepped skin. American Journal of Infection Control, 40(4):344-8.
5 Hensler J. et al. (2009). Growth inhibition of microorganisms involved in catheter-related infections by an antimicrobial transparent IV dressing containing Chlorehexidine gluconate (CHG). ECCMID, Helsinky, May 2009.
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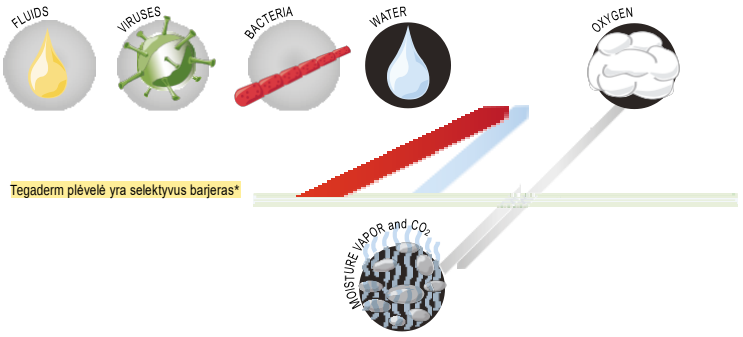


Tvarstis yra pralaidus orui ir leidžia pasišalinti drėgmei bei tuo pat metu apsaugo nuo teršalų, įskaitant tuos, kurie dažniausiai sukelia su kateteriu susijusias kraujo infekcijas.

Nepralaidus vandeniui, skysčiams virusams, bakterijoms, leidžiantis kvėpuoti odai tvarstis - plėvelė

**In vitro* tyrimai rodo, kad skaidri „Tegaderm CHG“ tvarsčio plėvelė sukuria 27 nm skersmens arba ilgesnį barjerą nuo virusų. Tvarstis tvirtai laikosi ir yra nepralaidus.[10]
Pastaba. „Tegaderm CHG“ tvarstis nėra skirtas pakeisti siūles, reikalingas naudojant trumpalaikius centrinės venos kateterius (pvz., jungo, poraktikaulinėje, šlaunies venose).

„3M™ Tegaderm™ CHG“ chlorheksidino gliukonato I.V. tvarsčiai

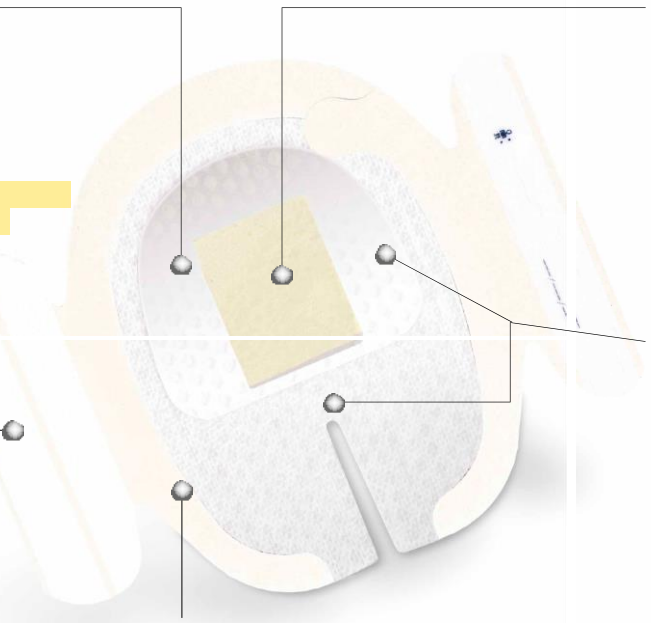
„Tegaderm CHG“ dar geriau apsaugo I. V. vietą, nes naudojamas CHG. Prie didesnio saugumo taip pat prisideda skaidrumas, patikimumas ir „3M™ Tegaderm™“ tvarsčio naudojimo paprastumas.

Visiškai orui laidi skaidri plėvelė

- Nuolatinis įvedimo vietos stebėjimas.
- Atitinka kūno formas ir prisitaiko pacientui judant.
- Skatina drėgmės pasišalinimą ir patikimą prilaikymą.
- Sukuria hermetišką, sterilų barjerą nuo išorinių teršalų, įskaitant skysčius, bakterijas ir virusus*
- Be latekso
- Pusiau peršlampamas ir orui laidus, kad geriau pasišalintų skysčiai bei pagerėtų prisitvirtinimas.

Sterilios juostelės

- Sukurta patikimam kateterio prilaikymui įvedimo vietoje.
- Atspausdintos etiketės tvarsčių keitimo dokumentavimui. Geresnis protokolo laikymasis.



CHG gelio pagalvėlė

- 2 % chlorheksidino gliukonatas
- Sugerianti CHG gelio pagalvėlė saugo, esant kraujui, fiziologiniam tirpalui ir išskyroms.
- CHG išskiriamas iškart ir nuolat, todėl nereikia papildomai drėkinti.
- Lipnios CHG gelio pagalvėlės prisitaiko prie kateterio.

Geresnis kateterio prilaikymas

- Sutvirtinti kraštelia ir grioveliai, kad tvirčiau laikytųsi.
- Minkšto audinio kraštelis puikiai prikimba ir suformuoja apsauginę zoną aplink kateterį.
- Raštuota plėvelė tvirtai prikimba, reguliuoja drėgnumą ir švelniai nusiima.
- Plėvelę prispaudus, klijai patenka į odos nelygumus ir padidina prikibimo plotą.
- Klijai sukietėja per 24 valandas.

Patogi naudojimo sistema su rankenėlėmis

- 2 rankenėlės, kad būtų patogiau uždėti neliečiant tvarsčio.
- Dėl konstrukcijos, uždedama tiksliai ir lengvai.
- Sumažina prikibimo prie pirštinių ar odos riziką.

Tvarstis su rėmeliu

**In vitro* tyrimai rodo, kad skaidri „Tegaderm CHG“ tvarsčio plėvelė sukuria 27 nm skersmens arba ilgesnį barjerą nuo virusų. Tvarstis tvirtai laikosi ir yra nepralaidus.[10]

Užsakymo informacija

		GAMINIO KODAS	BENDRAS TVARSČIO DYDIS	GELIO PAGALVĖLĖS DYDIS	PASKIRTIS	NHSSC KODAI	TVARSČIŲ / DĖŽUTĖJE	DĖŽUČIŲ PAKUOTĖJE
1.1 p.d.		**1657R**	8,5 cm x 11,5 cm	3 cm x 4 cm	Visi CVS, arterijų, dializės, vidurio linijos ir kiti perkutaniniai įtaisai	ELW294	25	4
1.2 p.d.		**1658R**	10 cm x 12 cm	3 cm x 4 cm	Visi CVS, arterijų, dializės, vidurio linijos ir kiti perkutaniniai įtaisai	ELW625	25	4
1.4 p.d		**1659R**	10 cm x 15,5 cm	3 cm x 7 cm	PICC linijos, visi CVC ir kiti perkutaniniai įtaisai	ELW295	25	4
1.3 p.d.		**1660R**	7 cm x 8,5 cm	2 cm x 2 cm	Visi CVC, vidurio linijos ir kiti perkutaniniai įtaisai	ELW366	25	4

Norėdami daugiau sužinoti apie „Tegaderm CHG“ tvarsčius arba visus „Tegaderm“ I. V. tvarsčius, apsilankykite adresu www.3m.com/tegadermchg

Daugiau informacijos suteiks vietinis „3M Critical and Chronic Care“ atstovas.

www.3m.co.uk/healthcare

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Product Description

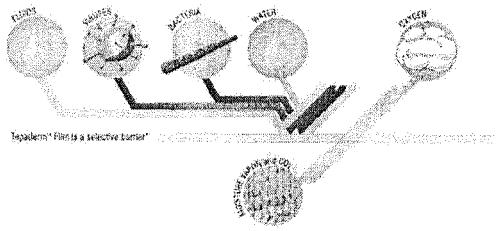
3M™ Tegaderm™ and Tegaderm™ HP Transparent Film Dressings consist of a thin film backing with a hypoallergenic, latex-free adhesive that gently, yet securely, adheres to skin. Tegaderm™ dressings are breathable, sterile, transparent and waterproof, and provide a barrier to external contaminants.

Hipoderminiai klijai. Pleistras be latekso.

Tegaderm™ HP Film has a special adhesive for greater holding power in the presence of moisture.

Specially designed Tegaderm™ dressings, with unique shapes and securing tapes provide solutions for difficult to dress wounds and I.V. catheters.

Product Features and Benefits



Tegaderm™ dressings are breathable, sterile, transparent and waterproof, and provide a barrier to external contaminants.

Versatile—one product to satisfy many clinical situations

Tegaderm™ dressings can be used to protect I.V. sites, enhance wound healing, prevent skin breakdown, and protect clean, closed surgical incisions.

Tegaderm™ dressings are available in many sizes, shapes and application styles to meet a wide variety of needs.

The frame allows the dressings to be tailored for special applications, when desired. Application systems of most other transparent dressings do not allow for this customization.

Easy to apply—unique frame delivery system

Application of Tegaderm™ dressing is intuitive and quick, making it easy to remember and easy to teach. It is especially convenient for patient self-care.

Tegaderm™ dressing minimizes application time and saves dressing waste and costs. The frame delivery system provides maximum control of the thin film for rapid application of even the largest dressings. The unique "picture-frame" allows precise and secure placement of the dressing every time. If the adhesive surface accidentally touches itself, the dressing can be separated and applied, eliminating wasted dressings.

Tegaderm™ dressing is also available in a first-aid style delivery system for the health care professional who prefers this application method.

Gentle adhesive—just the right balance in adhesive strength

Tegaderm™ dressings are made with a hypoallergenic, latex-free adhesive that is gentle to the skin, yet securely holds catheters and other devices in place.

Tegaderm™ dressing provides good initial adhesion without building to excessive levels over time. Even for dressings left in place for extended periods, the risk of patient discomfort and skin trauma is minimal when the dressing is properly removed.

The hydrophilic nature of the Tegaderm™ HP Film adhesive makes it exceptionally adherent and useful for moist conditions and difficult-to-dress areas. It provides extra holding power, reducing unscheduled dressing changes.

Breathable—lets oxygen in and moisture vapor out

The breathability of Tegaderm™ dressings allows moisture vapor and gas exchange, which is essential to maintain normal skin function under the dressing. **Leidžia odai kvėpuoti**

Patients can wear Tegaderm™ dressings for extended periods of time, with minimal risk of skin irritation or maceration, and without excessive proliferation of skin flora.

Waterproof, sterile barrier—impervious to liquids, bacteria and viruses*

Tegaderm™ dressing acts as a barrier to protect the I.V. site or wound from external contaminants such as bacteria, viruses,* blood and body fluids.

Because Tegaderm™ dressings are waterproof, patients may bathe, shower or swim, if the dressing is completely sealed around the catheter or wound. **Nepralaidus vandeniui**

Tegaderm™ dressing is sterile and remains so as long as the outer package is intact. Do not resterilize by gamma, steam, or E-beam. **Sterilus**

* *In vitro* testing shows that the transparent film of 3M™ Tegaderm™ brand dressings provide a viral barrier for viruses 27 nm in diameter or larger while the dressing remains intact without leakage.

3M News

3M Tegaderm CHG I.V. Securement Dressing Receives FDA 510(k) Clearance for Expanded Indication to Reduce Catheter-Related Bloodstream Infection

ST. PAUL, MINN. June 6, 2017 – Catheter-related bloodstream infections (CRBSI) are life-threatening for patients and costly for the medical professionals and facilities caring for them. 3M is pleased to announce that the U.S. Food and Drug Administration (FDA) has recognized the efficacy of 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing in reducing CRBSI, expanding the product's 510(k) indication to include CRBSI reduction.

The expanded indication is supported by a randomized, multi-arm, controlled clinical trial of 1,879 subjects that found Tegaderm CHG I.V. Securement Dressing reduced CRBSI by 60 percent in patients with central and arterial lines (p=0.020).[1]

"While we are making great strides in reducing CRBSI nationwide, these preventable infections are still responsible for significant morbidity, mortality and excess costs," stated Pat Parks, MD, PhD, medical director for 3M Critical and Chronic Care Solutions Division. "Successful CRBSI prevention practices rely on dedicated clinicians using proven technology, such as Tegaderm CHG I.V. Securement Dressing, in alignment with current best practice standards."

Tegaderm CHG I.V. Securement Dressing is the only transparent dressing indicated and proven to reduce CRBSI and vascular catheter colonization that aligns with evidence-based guidelines and practice standards. The dressing provides four essential elements to cover and protect patients' catheter sites and secure devices to skin.

- Infection Reduction: Clinically proven to reduce CRBSI by 60 percent in patients with central and arterial lines. The dressing features an integrated gel pad containing 2 percent w/w CHG, a

[1] Timsit JF et al. *Randomized controlled trial of chlorhexidine dressing and highly adhesive dressing for preventing catheter-related infections in critically ill adults*. Am J Crit Care Med. 2012;186(12): 1272-1278 http://www.atsjournals.org/doi/pdf/10.1164/rccm.201206-1038OC.

well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity that maintains antimicrobial activity for 10 days. Antimikrobinis poveikis išlieka 10 parų

- Site Visibility: Transparent film and gel pad allow for continual site observation, enabling early identification of complications at the insertion site.
- Consistent Application: Integrated CHG gel pad and dressing design ensure standardized, correct application.
- Catheter Securement: Designed to minimize catheter movement and dislodgement.

“Providing effective, proven technology such as Tegaderm CHG I.V. Securement Dressing is just one of the ways that 3M partners with clinicians to help them achieve their infection prevention goals,” said Parks. “We also provide clinical expertise and tools to support training and compliance, and engaging educational resources to help facilities implement the latest evidence-based guidelines and standards.”

For more information about coordinating a Tegaderm CHG Dressing product trial, please visit 3M.com/TegadermCHG.

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About 3M
At 3M, we apply science in collaborative ways to improve lives daily. With $30 billion in sales, our 90,000 employees connect with customers all around the world. Learn more about 3M’s creative solutions to the world’s problems at www.3M.com or on Twitter @3M or @3MNewsroom.

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3M

Tegaderm™ CHG

STERILE EO

3½ in x 4½ in
8,5 cm x 11,5 cm
REF 1657R

1

(GB) Chlorhexidine Gluconate I.V. Securement Dressing (Gel pad contains 2% w/w CHG)
(FR) Pansement au gluconate de chlorhexidine pour le maintien des cathéters intravasculaires
(DE) Chlorhexidin-Gluconat I.V.-Fixierverband
(IT) Medicazione di fissaggio I.V. con Clorexidina Gluconata
(ES) Apósito con gluconato de clorhexidina para fijación de catéteres
(NL) Chloorhexidinegluconaat I.V. verband
(SE) I.V.-förband med klorhexidinglukonat
(DK) Forbinding med Klorhexidin Glukonat til fastgørelse af I.V. kateter
(NO) Klorheksidinglukonat I.V. -beskyttelsesbandasje
(FI) Klooriheksidiiniglukonaatti I.V. -suojasidos
(PT) Penso I.V. com Gluconato de Clorohexidina
(RU) Повязка для фиксации внутривенных катетеров с хлоргексидина глюконатом
(KZ) Хлоргексидин глюконатын ТІ егетін катетерді бекітуге арналған жапсырма
(JP) テガダーム™ CHG ドレッシング
(CN) 抗菌靜脈注射固定用防水透氣敷料
(KR) CHG(글루콘산 클로르헥시딘) I.V. 고정 드레싱

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3M.com/Tegaderm

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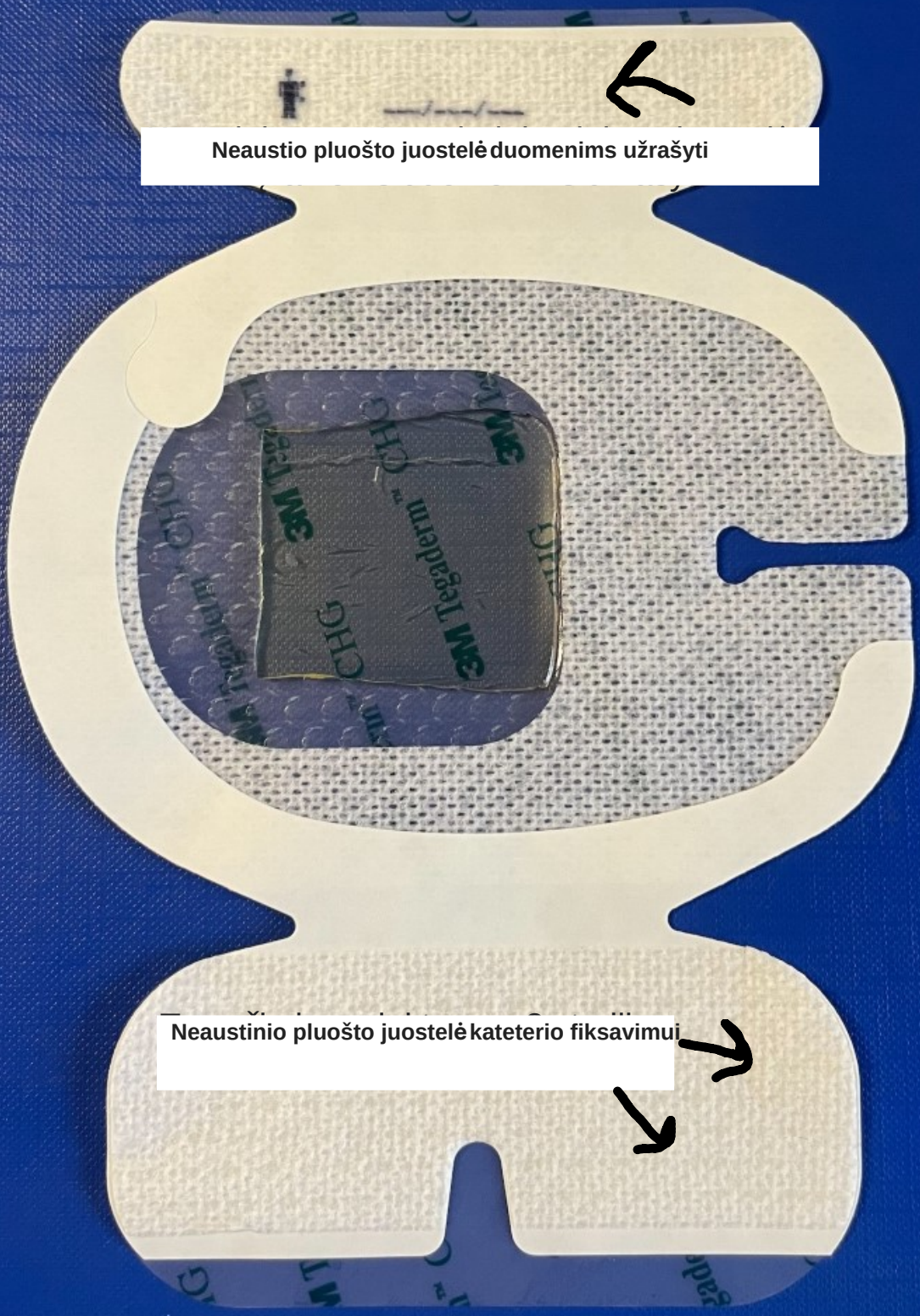
2024-04-16
REF 1657R

Permatoma plėvelė per pusę kombinuota su neaustinio pluošto pleistru
Tvarsčio centre integruota antimokrobinio poveikio gelio pagalvėlė.
Gelio pagalvėlė ir tvarstis permatomi, todėl leidžia stebėti dūrio vietą.



Tvarsčiai supakuoti steriliuose dalinai permatomuose įpakavimuose,
kurie leidžia vizualiai, neatidarius įpakavimo, įvertinti tvarsčio dydžio tinkamumą.

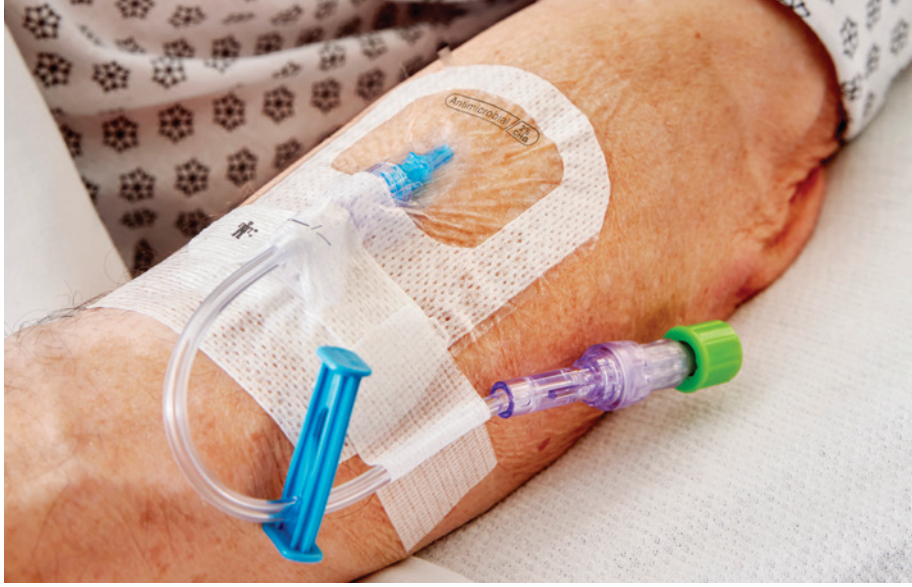
3M Science. Applied to Life.™

1.5 pirkimo dalis

Make peripheral lines a central focus.

Reduce the risk for PIV catheter complications.

Putting a focus on peripheral lines.

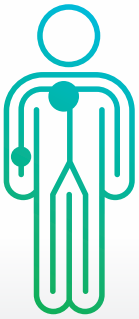


Peripheral intravenous (PIV) access is often considered a simple, low-risk procedure, when in fact:

Up to

70%

of patients receive a PIV catheter during their hospital stay.[1]

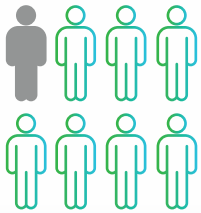


16–23%

of bacteremia originate from a peripheral catheter.[2,3,4]

12.7%

mortality rate forpatients with CRBSI originating from PIVCs.[5]



All IVs have the potential to be contaminated.

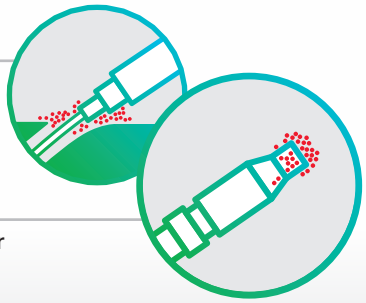
Hospital-acquired bloodstream infections resulting from vascular access can be acquired at the time of the initial insertion or throughout the duration of venous access.

Extraluminal contamination

Bacteria originates on the skin surface.

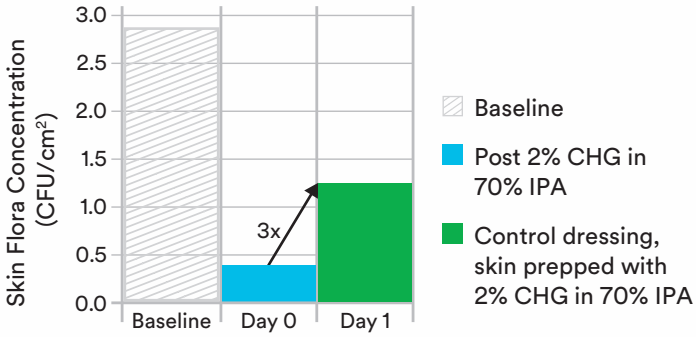
Intraluminal contamination

Bacteria enters via the catheter hub or IV access point.



There are multiple challenges to managing infection risks from PIVs.

Chlorhexidine gluconate (CHG) and isopropyl alcohol (IPA) skin preps can effectively clean the skin at the insertion site, but they cannot sterilise the skin. Microbes remain and can triple in volume as quickly as 24 hours following skin antisepsis.[6]



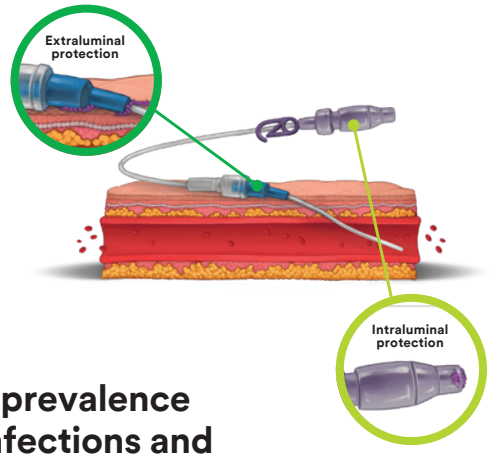
Prevention in practice: PIV care and maintenance guidelines.

We're proud to partner with you to help reduce the risk of PIV complications through evidence-based practice. We believe having the right standards of care, combined with the latest technology can help improve outcomes for every patient. Review these care and maintenance recommendations from around the world:

	Recommendation	INS 2021	RCN 2016	epic3 2014	CDC 2011
Prepare and assess 	Choose upper extremity for insertion	●	●	●	●
	Avoid areas of flexion	●	●		
	Designate personnel with IV therapy education, training and competency	●	●		●
	Smallest gauge indicated	●	●		
Insertion 	Prepare skin with antiseptic, allow site to dry	●	●	●	●
	Practice aseptic technique	●	●	●	●
Secure and protect 	Consider a securement dressing/device	●	●		●
	Use a sterile, transparent, semi-permeable polyurethane dressing	●	●	●	●
	Change dressing at least every 7 days or sooner if compromised	●	●	●	●
	Visually inspect insertion site at regular intervals	●	●	●	
	Monitor and track adverse events regularly	●	●		
	Disinfect injection port/access site before each access	●	●	●	●
	Consider use of disinfecting caps on access sites	●	●		
Remove 	Remove PIV catheters when clinically indicated	●	●	●	
	Remove emergently placed catheters asap, within 24–48 hours	●			●

See the evidence for yourself.

An often-overlooked risk: With more than 115 million[7] peripheral venous catheters (PVCs) inserted in West Europe alone, numerous PVC complications are bound to occur annually.



22%
of bacteremia originated from peripheral catheters[3]

German national point prevalence study on nosocomial infections and antibiotics use – 2016 final report

NRZ – Nationales Referenzzentrum für Surveillance von nosokomiale Infektionen.

Results:
From all nosocomial infections associated with a vascular catheter, 22% were attributed to a peripheral intravenous catheter.

View abstract:
https://www.nrz-hygiene.de/fileadmin/nrz/download/pps2016/PPS_2016_Abschlussbericht_20.07.2017.pdf

Short-term PVCs accounted for
23%
of hospital-acquired catheter-related bloodstream infections (CRBSIs)

Short-term peripheral venous catheter-related bloodstream infections: A systematic review

Mermel L. *Clinical Infectious Diseases.* 2017;65(10).

Results:
A systematic review of 63 studies determined that the incidence of PVC-related BSIs was 0.18% among 85,063 PVCs. 38% of healthcare-associated *S. aureus* CRBSIs are due to PIVs.[4]

View abstract:
https://www.ncbi.nlm.nih.gov/pubmed/29020252

Catheter-related Phlebitis:	15.4%
Catheter infiltration:	23.9%
Catheter occlusion/ Mechanical failure:	18.8%
Catheter dislodgment:	6.9%
Catheter-related BSI (up to):	0.2%
PIV catheter failure rate:	**46%**

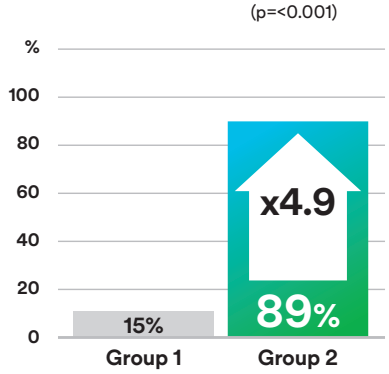
Accepted but unacceptable: Peripheral I.V. catheter failure

Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. *Journal of Infusion Nursing.* 2015;38(3).

Results:
A systematic review of at least 45 randomised controlled studies from 1990 to 2014 determined that PIV insertion is associated with a variety of complications.[8]

View study:
https://www.hemocat.com.br/upload/Acesso_Venoso_Periferico_Falhas.pdf

89% PIV catheters reaching end of therapy:



The PIV5Rights™ Bundle

Lee Steere *et al*, JAVA 2019

Results:
Outcomes of the PIV5Rights Bundle in Group 2.

Variable	Group 1 (n=94)	Group 2 (n=113)
Success rate (therapy completed)	15%	89%
Dwell time in hours (mean ± SD, P<0.001)	29.6 ± 18.0	71.4 ± 58.8
Complication rate (%, p<0.001)	40%	11%
Cost/bed/year (2018 USD)	$4,781	$1,405

View study:
https://doi.org/10.2309/j.java.2019.003.004

Help reduce the risk of PIV complications at all access points.

3M solutions help to protect against both extraluminal and intraluminal contamination of PIVs.

Extraluminal protection

	 3M™ Tegaderm™ Dressing 1624W/1623W	3M™ Tegaderm™ I.V. Dressing 1633	 3M™ Tegaderm™ I.V. Advanced Securement Dressing 1681/1683	 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing 9132
Antimicrobial protection				
Suppression of regrowth of skin flora at 1, 3, and 7 days				●
Advanced catheter securement				
Meets INS definition of integrated securement device* + ANTT application + superior moisture management			●	●
Catheter fixation				
Reinforces the insertion site with a soft cloth area around the notch		●	●	●
Catheter protection and site visibility				
Provides a waterproof, sterile barrier to external contaminants and a 7 day wear time	●	●	●	●

*full border/fabric collar with built-in securement technology and additional tape strips.

Intraluminal protection

Using a peripheral line bundle that includes Curos Disinfecting Caps and 3M™ Curos Tips™ Disinfecting Caps for Male Luers provides effective disinfection. Effective disinfection of needleless connectors and male luers on peripheral lines has been associated with a significant decrease in primary peripheral line-associated bloodstream infections (PLABSI).[9]

Skin protection

Skin is the body's first line of defense against infection.

Preparation of the skin and selection of proper adhesives are the first steps to help minimise the risks of skin damage.[10]

3M™ Cavilon™ No Sting Barrier Film

Forms a breathable, transparent and protective coating between the skin and the adhesive of the securement dressing, device or tape.

3M™ Micropore™ S Surgical Tape

Offers reliable adhesion and removes cleanly with minimal disruption of skin layers and without causing patients undue discomfort.[11] Individually packaged, single-patient-use rolls help reduce cross-contamination risk.*

*Individually packaged, single-patient-use rolls help prevent tape from being exposed to environmental contaminates, minimise contact with hospital surfaces and equipment, and exposure to healthcare worker hands.

Partner with 3M to make peripherals a central focus of your IV maintenance programme.

Extraluminal protection

		Product #	Size	Dressings/box	Boxes/case
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing		9132	7 cm x 8.5 cm	25	4
3M™ Tegaderm™ I.V. Advanced Securement Dressing		1681	7 cm x 8 cm	100	4
3M™ Tegaderm™ I.V. Advanced Securement Dressing		1683	6.5 cm x 7 cm	100	4
3M™ Tegaderm™ I.V. Advanced Securement Dressing		1682	5 cm x 5.7 cm	100	4
3M™ Tegaderm™ I.V. Advanced Securement Dressing		1680	3.8 cm x 4.5 cm	100	4

Intraluminal protection

		Product #	Description	Each/box	Boxes/case
3M™ Curos™ Disinfecting Caps for Needleless Connectors		CFF1-270R	Individuals	270	10
		CFF10-250R	Strips (5 count)	50 Strips	10
3M™ Curos Tips™ Disinfecting Caps for Male Luers		CM5-200R	Strips (5 count)	40 Strips	10
3M™ Curos™ Stopper Disinfecting Caps for Open Female Luers (Teal)		CSV1-270R	Individuals	270	8
		CSV5-250R	Strips (5 count)	50 Strips	8

Skin protection

		Product #	Size	Items/box	Boxes/case
3M™ Cavilon™ No Sting Barrier Film		3343	1 ml wand	25	4
3M™ Micropore™ S Surgical Tape (individually packaged, single-patient-use roll)		2770S-1	2.5 cm x 1.3 m	100	5

Important safety information for 3M™ Tegaderm™ CHG dressings
Do not use Tegaderm CHG dressings 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 I.V. Securement Dressings has not been established in children under 18 years of age. For full prescribing information, see the Instructions for Use (IFU). Rx Only.

To learn more or to schedule a product evaluation, visit us at **3M.co.uk/PIVCare**

1 Zingg W, Pittet D. Peripheral venous catheters: an under-evaluated problem. *Int J Antimicrob Agents.* 2009;39(4):S38–S42.

2 Van Der Mee N. Surveillance et Prevention des Infections asscociées aux dispostifis invasifs, SPIADI 2020. https://www.spiadi.fr/app/files/nvdm.98a63188c9af649403416a98eb2d5dce.pdf

3 Nationales Referenzzentrum für die Surveillance von nosokomialen Infektionen. Deutsche nationale Punkt-Prävalenzerhebung zu nosokomialen Infektionen und Antibiotika-Anwendung 2016 Abschlussbericht. Online im Internet unter: https://www.nrz-hygiene.de/fileadmin/nrz/download/pps2016/PPS_2016_Abschlussbericht_20.07.2017.pdf

4 Mermel L. Short-term Peripheral Venous Catheter-Related Bloodstream Infections: A Systematic Review. *Clin Infect Dis.* 2017:65(10):1757–1762.

5 Saliba P, Hornero A, Cuervo G, Grau I, Jimenez E, García D, Tubau F, Martínez-Sánchez JM, Carratalà J, Pujol M. Mortality risk factors among non-ICU patients with nosocomial vascular catheter-related bloodstream infections: a prospective cohort study. *J Hosp Infect.* 2018 May;99(1):48–54.

6 3M data on file.

7 Data 2020.

8 Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: Peripheral IV catheter failure. *J Infus Nurs.* 2015;38(3):189-203.

9 Steere L, Davis M, Moureau N. Reaching One Peripheral Intravenous Catheter (PIVC) Per Patient Visit with LEAN multi-modal strategy: The PIV5Rights Bundle. *JAVA.* 2019;24(3).

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OMG321133.

Antimicrobial
2% CHG
Dressing with 2% CHG
3M | Tegaderm™
Dressing with 2% CHG

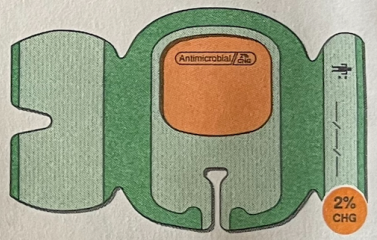
3M | Tegaderm™

STERILE EO

REF 9132

Antimicrobial I.V. Advanced Securement Dressing

(en) Antimicrobial I.V. Advanced Securement Dressing
(fr) Pansement antimicrobien de maintien avancé pour cathéters intraveineux
(de) I.V. Advanced Antimikrobieller Fixierverband
(it) Medicazione di fissaggio IV avanzata ad azione battericida
(es) Apósito de fijación avanzada IV antimicrobiano
(nl) Antimicrobieel geavanceerd fixatieverband, infuus
(sv) Antimikrobiskt IV avancerat säkert såromslag
(da) Antimikrobiel IV avanceret fikseringsforbinding
(no) Antimikrobiell avansert beskyttende IV-bandasje
(fi) Antimikrobinen I.V. Advanced -suojasidos
(pt) Penso Antimicrobiano para Fixação Avançada de Cateteres IV
(el) Αντιμικροβιακό Επίθεμα Προηγμένης Συγκράτησης για Ενδοφλέβιες Χορηγήσεις
(pl) Bakteriobójczy, zaawansowany opatrunek do mocowania wkłuć naczyniowych
(hu) Antimikrobiális hatású, továbbfejlesztett kötszer intravénás kanül rögzítéséhez
(cs) Antimikrobiální krycí obvaz IV Advanced
(sk) Antimikrobiálne krytie na pokročilé IV zaistenie
(sl) Protimikrobna IV napredna pritrdilna obveza
(et) Antimikroobne IV täiustatud paigalhoidev haavaside
(lv) Antimikrobiāls uzlabotas fiksācijas IV pārsējs
(lt) Antimikrobinis IV pažangusis apsauginis tvarstis
(ro) Pansament de fixare avansat IV antimicrobian
(ru) Наклейка пленочная антимикробная для фиксации катетеров IV Advanced
(uk) Протимікробна пов'язка для покращеного кріплення катетера для внутрішньовенної ін'єкції
(hr) Napredni zavoj za osiguranje IV protiv mikroba
(bg) Антибактериална превръзка за подобрено фиксиране на интравенозни канюли
(sr) Napredni zavoj za obezbeđenje IV protiv mikroba
(tr) Antimikrobiyal IV Advanced Sabitleme Örtüsü
(kk) Микробтарға қарсы IV жетілдірілген бекіту жабыстырғышы
(sq) Fashë antimikrobike intravenoze e përparuar sigurie
(mk) Антимикробна преврска за канила со појака лепенка

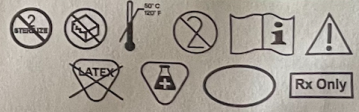


1 2.75 IN x 3.375 IN
7 cm x 8,5 cm

MD CE 2797

Made in U.S.A. with globally sourced materials
3M Company • 2510 Conway Ave., St. Paul, MN 55144 USA
1-800-228-3957 (USA only)

EC REP 3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany



Rx Only

LOT 33NNF4
2024-03-03
(01)00707367793295
(11)220304
(17)240303(10)33NNF4

REF 9132
2022-03-04

UDI

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing

General Description

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing consists of a polyurethane film coated with a transparent chlorhexidine gluconate (2% CHG) acrylic adhesive. CHG, a broad spectrum antimicrobial/antifungal agent known to inhibit microbial growth has been formulated into the acrylic adhesive.

The transparent film is breathable, allowing oxygen and moisture vapor exchange, yet is impermeable to external contaminants, including fluids (waterproof), bacteria, viruses of 27nm in diameter or larger*, yeast and mold. The dressing must remain intact to protect the IV site from external contaminants.

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is bordered, notched and reinforced with soft cloth tape and is designed to provide securement around catheters and other devices. All parts of the dressing including tape strip and documentation label are covered with a waterproof polyurethane film providing edge-to-edge film protection.

In vitro testing (time kill) demonstrates that 3M™ Tegaderm™ Antimicrobial Transparent I.V. Advanced Securement Dressing has an antimicrobial effect against a variety of gram-positive bacteria, gram-negative bacteria, yeast and mold.

*In vitro testing shows that the film of the dressing provides a barrier to viruses 27 nm in diameter or larger while the dressing remains intact without leakage. These results have not been studied with regard to prevention of viral infection. No clinical study has been conducted regarding the ability of the dressing to prevent viral infections.

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is CE marked as a Class III medical device and complies with the needs and requirements of the European Medical Device Directive 93/42/EEC.

Note: This Document is valid for the European Union only. The registration status in other geographies must be confirmed.

Intended Use

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing are intended to be used to cover and protect catheter sites and to secure devices to the skin. Common applications include covering and securing IV catheters, other intravascular catheters and percutaneous devices.

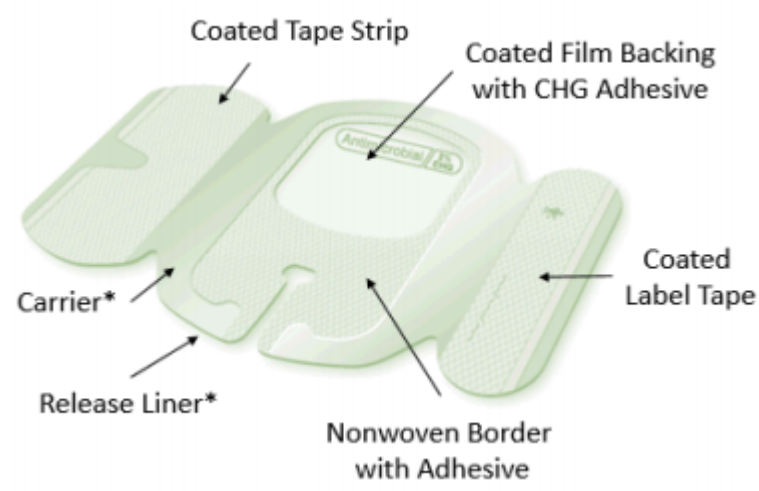
Contraindications

There are no contraindications for the product

Precautions and Warnings:

Please refer to the Instructions for Use (IFU) and especially note mucous membrane and age limitations.

Product Composition



Materials used for 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing

Family / Reference Number	Components	Material
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing: 9132	Coated Label Tape and Coated Tape Strip	a. Release Coating b. Polyurethane film c. Acrylic adhesive d. Nonwoven fiber e. Acrylic adhesive
	Carrier*	Paper
	Coated Film backing	a. Release Coating b. Polyurethane
	CHG Adhesive	a. Acrylic adhesive b. CHG
	Nonwoven border with adhesive	a. Nonwoven fiber b. Acrylic adhesive
	Release liner*	a. Silicone b. Polyester

Packaging Composition

Each dressing is packaged into a pouch. Several pouches are packaged into a primary carton. Then several cartons are placed in a shipper carton.

Packaging Level	Material	Content of recycled material in packaging
Pouch:	Heat-sealed, ethylene oxide permeable pouch (paper/plastic film)	Does not contain recycled material
Carton:	Clay coated, newsback (Material made from recycled paperboard and aqueous coating to protect the printing)	Minimum Post-Consumer Waste Recycled content 35% and maximum Recycled content 100%.
Shipper:	Corrugated box	May contain up to 100%" recycled content.

Product Range

Name of Product / Description	Reference number	Content Items per box/case
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing	9132	1 dressing/pouch 25 pouches/primary carton 4 primary cartons/master carton

GENERAL CHARACTERISTICS

Parameter	Product Performance	Test Method	Results
Fluid Barrier	Dressing provides a barrier to fluids (such as water, blood and wound exudates)	ASTM F1670	Pass
Viral Barrier	Dressing provides a barrier to viruses of 27nm in diameter or more	ASTM F1671	Pass
Microbe Barrier	Prevents entry of bacteria to skin surface	Bench Study	Pass
Moisture Management	Breathable/ Semi-permeable/ not occlusive/ Permeable to moisture vapor	Bench Test based on TS-7023A or EN 13726-2:2002	Confirmed Film/Border Upright MVTR (g/m2 /24hrs minimum): 250 Film/Border Inverted MVTR (g/m2 /24hrs minimum): 350
Visibility	Catheter insertion site is visible through the dressing	Clinical Study	Confirmed
Catheter stabilization	Holds catheters and appliances securely in place	Clinical Study	Confirmed
Radiological Compatibility	The dressing is compatible with MRI (Magnetic Resonance Imaging) (Does not distort the image) MR safe Radiologically transparent	ASTM-F2503-13 ASTM-F640-07 Procedure Method A	Confirmed Confirmed
Catheter Compatibility	The dressing is compatible with the majority of materials for PIV and CVC catheters, including polyurethane, silicone, FEP Teflon, BD Vialon TM etc.	Bench Study	Confirmed
Chemical Compatibility	The dressing is compatible for use with skin	Clinical Studies	Confirmed

Parameter	Product Performance	Test Method	Results
	antiseptics (i.e. IPA, PVPI, and Chlora prep®) The dressing is compatible for use with No-Sting Barrier Film (note: not closer than within 1 inch of catheter insertion site)		
Wear time	Each dressing can be safely worn for up to 7 days	Clinical Study	Confirmed
Waterproofness	Dressing provides a barrier to fluids (such as water, blood and wound exudates)	EN 13726	Pass
Direct Time Kill	CHG demonstrates broad-spectrum antimicrobial activity	Modified AATCC Test Method 100	Average 4log reduction compared to T0 control In vitro time kill testing demonstrates that the dressing has an antimicrobial effect against a variety of gram-positive and gram-negative bacteria, yeast and mold, including organisms most commonly found on skin and commonly associated with catheter related blood stream infection (CRBSI*) (≥ 4 log reduction) * This device is not intended to treat, prevent, or reduce catheter-related bloodstream infections (CRBSIs) or other percutaneous device-related infections. This device has not been studied in a

Parameter	Product Performance	Test Method	Results
			randomized clinical study to determine its effectiveness in preventing such infections
Sterility	Sterile unless package is damaged or opened	Sterilization validation	Pass
Shelf Life	2 year shelf life	Bench Study	Pass
Sustained antimicrobial efficacy	Maintains consistent antimicrobial activity for up to 7 days	Clinical Study	Confirmed
Suppress regrowth of normal skin flora	Studies on skin flora of healthy subjects showed significantly more reduction of skin flora with Tegaderm™ antimicrobial dressing at 1, 3, and 7 days compared to placebo non-antimicrobial dressing ($p<0.0001$) Tegaderm™ antimicrobial dressing is significantly more effective than the placebo non-antimicrobial dressing in reducing microbial counts on unprepped skin at 1, 3, and 7 days	Clinical Study	Confirmed
Antimicrobial Activity	Antimicrobial activity of the dressing is not compromised by simulated wound fluid challenging	Clinical Study	Confirmed
CHG Activation	No additional moisture is needed to activate CHG	Clinical Study	Confirmed

EASE OF USE

Parameter	Product Performance	Test Method	Results
Dressing Application	One-handed application is possible	3M Nurse Assessment	Pass
	Easy to apply integrated design	Customer Evaluation	Pass
	Delivery permits clinician to apply dressing without sticking to gloves	3M Nurse Assessment	Pass
	Dressing is easy to remove throughout 7 days without removal agents, stays intact during removal. Easy to initiate removal	Customer Evaluation	Pass

SAFETY AND SKIN TOLERABILITY (1)
All tests conducted according to GLP (good laboratory practice) as described by the FDA (21CFR Part 58) and according respective EU standards

Parameter	Product Performance	Test Method	Results
Basic safety	Product is safe for intended use Product is safe for its intended use as a surface device with prolonged (< 30 days) contact of breached or compromised skin. Not for use on premature infants or persons with known sensitivity to CHG	ISO 10993-Part 1 (biological evaluation of medical devices- evaluation and testing)	In compliance
		ISO 14971 (application of risk management to medical devices	In compliance- All documentation completed
Cytotoxicity	The 3M CHG adhesive dressing was found to be non-cytotoxic in the MEM Elution Assay	ISO 10993-5	In compliance
Skin irritation	Non-irritating	ISO 10993-10	In compliance
Skin Sensitization	Non-sensitizing	Guinea Pig Maximisation Test (Magnussen Klingman) ISO 10993-10	In compliance

SAFETY AND SKIN TOLERABILITY (2)

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of toxic compounds	Contains No health hazard chemical compounds	Raw Material Information, Formulation, Composition, LCM	No toxicological concerns identified for any component chemicals
	Free of: - PVC - Natural rubber latex - Colophony	Raw Material Information, Formulation, Composition, LCM	Confirmed
	Contains antimicrobial compounds (CHG).	Raw Material Information, Formulation, Composition, LCM	Confirmed
Basic safety/ absence of Substances of Very High Concern	The substances of the REACH SVHC candidate list as of 10th June 2022 are not present at or above 0,1%	Raw Material Information, Formulation, Composition	confirmed

PACKAGING RELATED INFORMATION

Packaging standards

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	ISO 15223	In compliance
Sterile Barrier System (SBS)	Sterile unless package is damaged or opened	EN ISO 11607- Part 1&2	In compliance
Undesirable components of packaging	Free of substances of very high concern (SVHCs) in >0,1% in weight concentration	EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU	Stated in supplier contracts
Undesirable components of packaging	Free of PVC (polyvinylchloride) Free of silica gel Totally Chlorine Free bleaching	3M internal standards	Stated in supplier contracts
Undesirable components of packaging	Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight)	Article 9 of EC directive 94/62/EC	Stated in supplier contracts

CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Certificate Number
ISO 13485	3M Company 3M Health Care 2510 Conway Ave Saint Paul, Minnesota 55144 Unites States	BSI	FM68740
93/42/EEC Annex II	3M Company 3M Health Care 2510 Conway Ave Saint Paul, Minnesota 55144 Unites States	BSI	CE 698003 CE 02242

Shelf Life Information

2 years shelf-life at room temperature.

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
3M Deutschland GmbH, Health Care Business, Carl-Schurz-Str. 1, 41453 Neuss, Germany

3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company, 3M Health Care,
3M Center, 2510 Conway Ave, Bldg. 275-5W-06
Saint Paul, MN 55144 USA

hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Tegaderm™ Antimicrobial Transparent Dressing
and
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing
(containing chlorhexidine gluconate)
Product Numbers:
9124 and 9132

is classified,
per Rule 13 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class III device
and

is in accordance with Annex II of Directive 93/42/EEC, as amended per 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices.

In addition, we declare that the above mentioned device fulfils the applicable provisions of the Directive 93/42/EEC, as amended per 2007/47/EC.
and

are in conformity with the type described in the EC Type-Examination certificate reference number: CE 698003 and the full quality assurance certificate EC 02242 delivered by British Standards Institute (BSI), Notified Body Number 2797

EU Representative Address
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

REG-DOC-05-362965, Tegaderm Antimicrobial Transparent Dressing and Tegaderm Antimicrobial I.V. Advanced Securement Dressing DOC, Version 2,
Status: Review, Release Date: <<Release Date>>

THIS DOCUMENT WAS PRINTED ON 24-Mar-2022 1:23 PM

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725198 R000

Manufacturer: 3M Company

Address:
2510 Conway Avenue
Saint Paul
Minnesota
55144
USA

Single Registration Number: US-MF-000014086

EU Authorised Representative: 3M Deutschland GmbH

Address:
Healthcare Business
Carl-Schurz-Str. 1
41443 Neuss
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

First Issue Date: **2024-03-06**

Starting Validity Date: **2024-05-29**

Current Issue Date: **2024-05-29**

Expiry Date: **2029-03-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725198 R000

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
3M™ Tegaderm™ Antimicrobial Transparent Dressing	9124	MDN 1204	Intended to be used to cover and protect catheter sites and to secure devices to the skin. Common applications include covering and securing IV catheters, other intravascular catheters, and percutaneous devices	Class III	06082238401010000000191AU
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing	9132				

First Issue Date: **2024-03-06**

Current Issue Date: **2024-05-29**

Starting Validity Date: **2024-05-29**

Expiry Date: **2029-03-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725198 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-03-06	3154355	Issued
2024-04-23	30111255	Amended - Addition of ethylene oxide sterilisation subcontractor
Current	30109068	Amended – Specification change

First Issue Date: **2024-03-06**

Current Issue Date: **2024-05-29**

Starting Validity Date: **2024-05-29**

Expiry Date: **2029-03-05**

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EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked devices

Trade Name	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing
Intended Purpose	Used to cover and protect catheter sites and to secure devices to skin; intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.
Reference	1657R, 1658R, 1659R, 1660R, 1877R, 1879R
Basic UDI-DI	06082238401010000000129Z

are classified per rules 4 and 14 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class III devices in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the Quality Management System Certificate and Technical Documentation Assessment Certificate.

EU Quality Management System Certificate Number: MDR 725200
EU Technical Documentation Assessment Certificate: MDR 725050
Issued by: BSI, 2797

EU Authorized Representative:

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-AR-000011642
Carl-Schurz-Str. 1

By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725050 R000

Manufacturer: 3M Company

Address:
2510 Conway Avenue
Saint Paul
Minnesota
55144
USA

Single Registration Number: US-MF-000014086

EU Authorised Representative: 3M Deutschland GmbH

Address:
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

First Issue Date: **2022-09-12**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

Expiry Date: **2027-09-11**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725050 R000

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing	1657R 1658R 1659R 1660R 1877R 1879R	MDN 1204	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. The dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to blood stream infections and to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	Class III	60822384010100000000129Z

First Issue Date: **2022-09-12**

Current Issue Date: **2024-04-19**

Starting Validity Date: **2024-04-19**

Expiry Date: **2027-09-11**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 725050 R000

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad	1664R	MDN 1204	Can be used to protect catheter sites. Common applications include protecting intravascular catheters and percutaneous devices. The dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to bloodstream infections and to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	Class III	06082238401010000000039AM

First Issue Date: **2022-09-12**

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Expiry Date: **2027-09-11**

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EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked devices

Trade Name	3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing
Intended Purpose	Used to cover and protect catheter sites and to secure devices to skin; intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.
Reference	1657R, 1658R, 1659R, 1660R, 1877R, 1879R
Basic UDI-DI	06082238401010000000129Z

are classified per rules 4 and 14 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class III devices in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the Quality Management System Certificate and Technical Documentation Assessment Certificate.

EU Quality Management System Certificate Number: MDR 725200
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Issued by: BSI, 2797

EU Authorized Representative:

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-AR-000011642
Carl-Schurz-Str. 1