

C O N F I D E N T I A L

11, 12 pozicijos

SoFilmPlus[®]

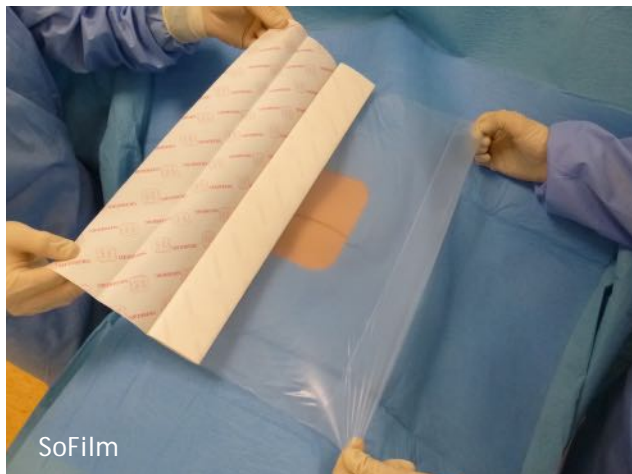
PRODUCT LAUNCH INFORMATION



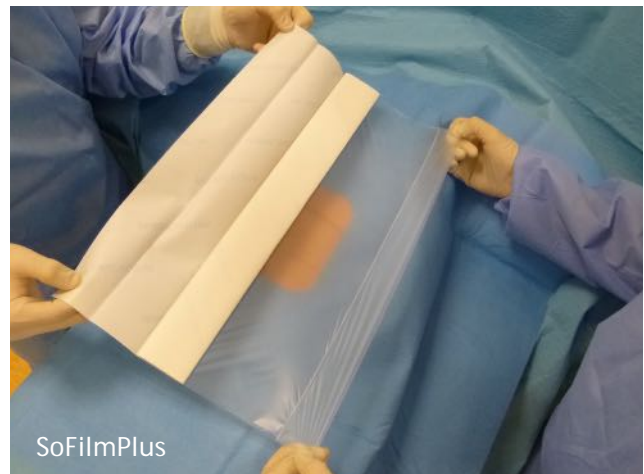
Somed

1. Product concept

1.1. Appearance 11 poz



12 poz



plėvelė turi du nelimpančius kraštus



Construction

- 1) Polyurethane carrier
- 2) Adhesive with silver ions
- 3) Release liner white with ANTIMICROBIAL print

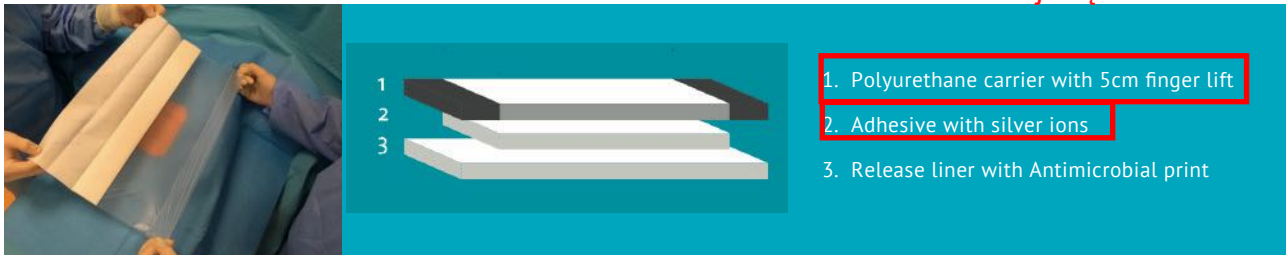
1.2. Surgical Site Infections

Surgical-site infections are an important health care problem and may result in significantly more post-surgical complications, lengthier hospital stays and increased mortality.

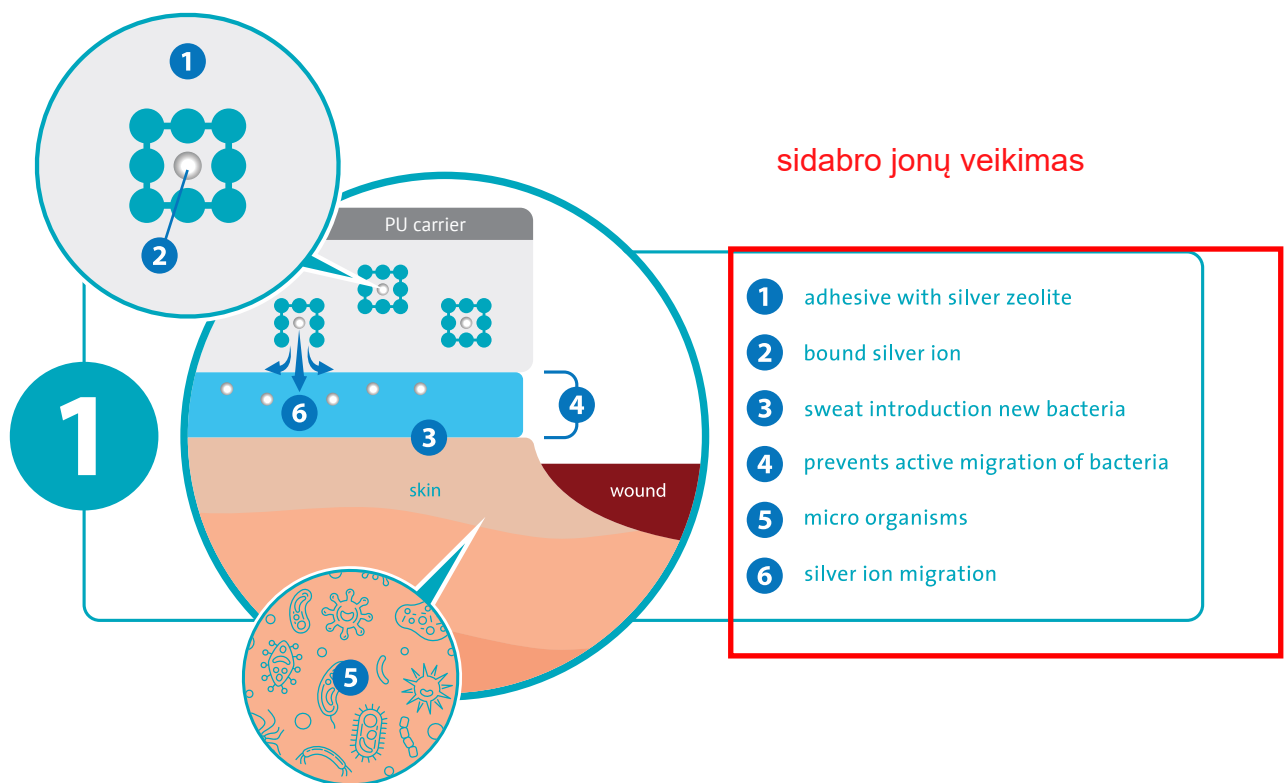
Incision films are a surgeon's best allies for reducing microbial proliferation and minimising the incidence of trans- and post-operative infections, which have always been a serious problem for the patient's health and an important cost-driver for the health care industry.

1.9. Sales Points and Major properties

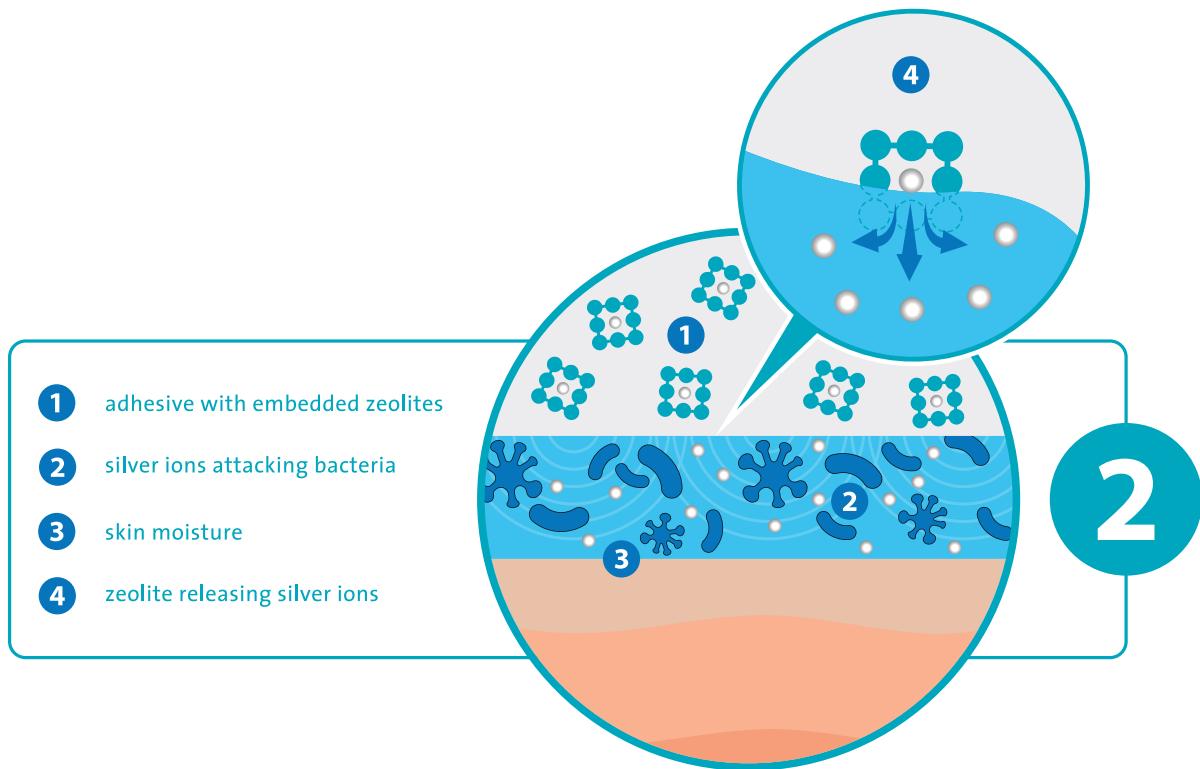
sidabro jonų veikimas



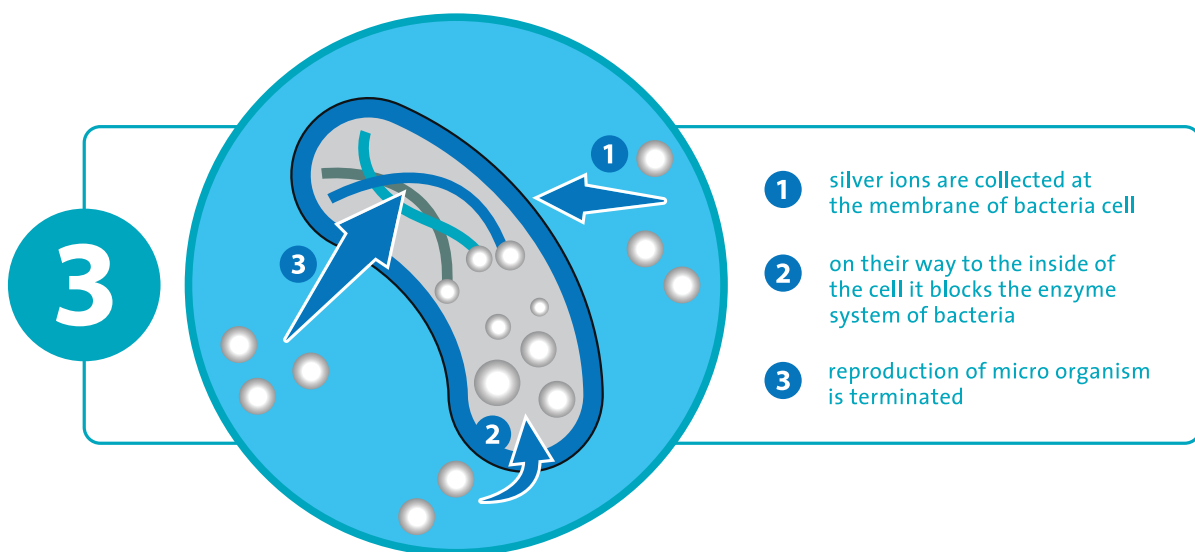
You have a sterile area, the only place where microorganisms can still be introduced is from the skin in the form of sweat. the film keeps the area sterile between the moment of disinfection and incision and that is especially the moment that it is necessary, so that if you cut you do not cut a micro-organism into the skin and that remains sterile outside the wound during the operation.



The moment the incision film comes into contact with sweat, a bridge forms with the zeolite structure and the bacteria that are introduced there. The silver is bound to the zeolite as a positive ion and comes into contact with water (is exchanged with another positive ion) so that the silver that is now in water can start with the termination of bacteria



By osmosis (such as two cups of water a cold and a warm connect with each other than over time are equal), it is possible for the silver ion to enter through the cell membrane. Outside, silver concentration is higher than inside, and a balance is needed. It is well known that silver has a killing effect on bacteria and once it is inside the process can begin.



2. Product specifications

2.1. Product description and application

SoFilm and SoFilmPlus are sterile incision films.

SoFilm and SoFilmPlus are intended to be applied on the patient's skin for covering and protecting during surgical interventions. The incision is made through the film. SoFilmPlus is enhanced with active silver ions for a continuous antimicrobial effect.

SoFilm and SoFilmPlus are consisting of:

- a transparent polyurethane film (1);
- single adhesive coated (2);
- covered with a 120 grams release liner (3) and
- a 5cm wide transparent finger lift.



skaidri poliuretano plėvelė, padengta lipdnia danga

SoFilm and SoFilmPlus are individually wrapped, pouched and sterilised by EO.

SoFilm

UV cured, acrylic based, pressure- and temperature-sensitive hotmelt adhesive.

padengti hipoalerginiai
akriliniai klėjais

MEDIBERG print on the release liner



SoFilmPlus

UV cured, acrylic based, pressure- and temperature-sensitive hotmelt adhesive with antimicrobial effect

padengti hipoalerginiai
akriliniai klėjais, kurioje yra atimikrobinė
veikloji medžiaga

ANTIMICROBIAL print on the release liner



2.4. Antimicrobial efficacy

Disinfectant on the human skin

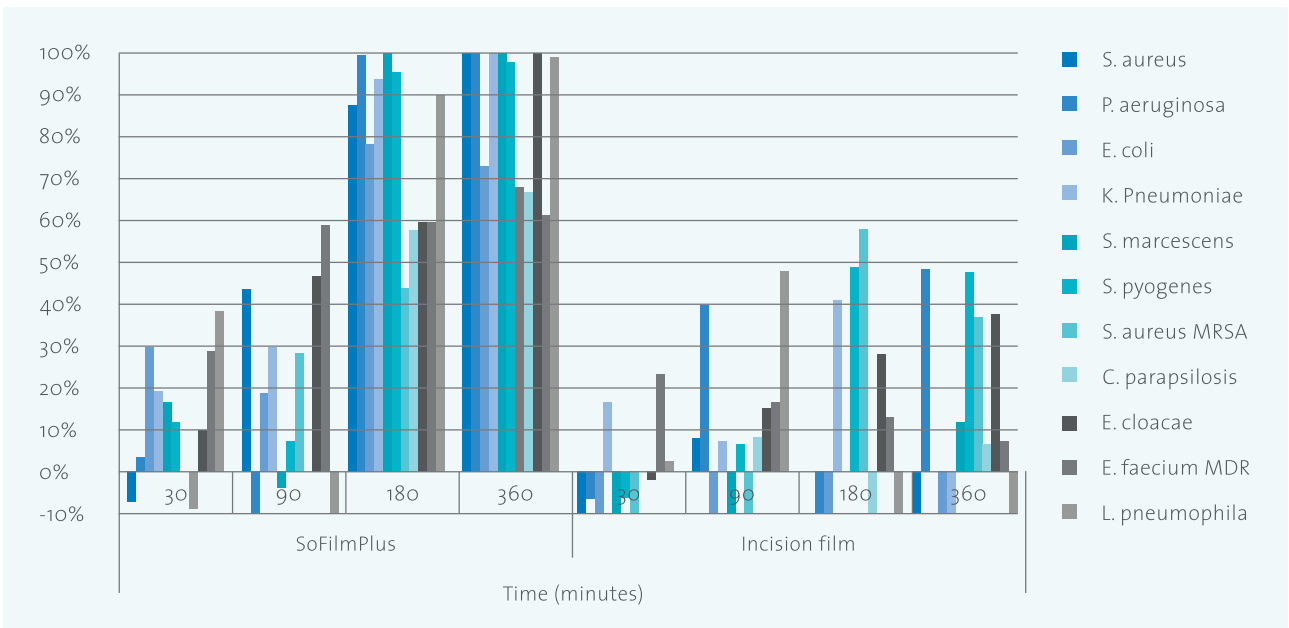
As part of the infection-prevention protocol, disinfectant is applied to the patient's skin in the surgical area before the intervention. However, bacteria spontaneously recolonise the disinfected area of the skin 30 to 60 minutes after disinfection.

sample	before desinfection	† 0 minutes	† 60 minutes
1) Cutasept F (72% Isopropanol + Benzalconium chloride)			
2) AddedPharma Hand disinfectant (Chlorhexidingluconate 0.5% + Alcohol 70%)			

Test laboratory: Quality Labs BT GmbH, 29-Sept-2016

Type of test: Antimicrobial Efficacy Testing of Disinfectants on Material surfaces

A study was conducted on the test product SoFilmPlus in order to determine its antibacterial effectiveness compared to regular incision film.



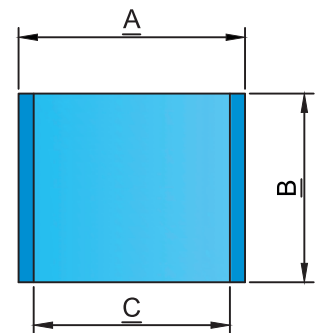
Test laboratory: Eurofins Biolab s.r.l., 01-Feb-2016

Type of test: ASTM E-2180-07: Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials

2.5. Dimensions

SoFilm and SoFilmPlus are available in the following dimensions.

Outer dimension A x B	Dimension adhesive area C x B
25cm x 20cm	15cm x 20cm
50cm x 35cm	40cm x 35cm
50cm x 45cm	40cm x 45cm
65cm x 45cm	55cm x 45cm
65cm x 60cm	55cm x 60cm
95cm x 65cm	85cm x 65cm
65cm x 85cm	55cm x 85cm



2.6. Product numbers and names

SoFilm

matmenys lipnios dalies

Product number	EAN code (UDI)	Product name
305001GBZSME	8030413102611	SoFilm 25cm x 20cm
305003GBZSME	8030413102772	SoFilm 50cm x 35cm
305004GBZSME	8030413102857	SoFilm 50cm x 45cm
305005GBZSME	8030413102932	SoFilm 65cm x 45cm
305006GBZSME	8030413103014	SoFilm 65cm x 60cm
305007GBZSME	8030413103090	SoFilm 95cm x 65cm
305011GBZSME	8030413103267	SoFilm 65cm x 85cm

11 poz

SoFilmPlus

matmenys lipnios dalies

Product number	EAN code (UDI)	Product name
306001GGZSME	8030413103502	SoFilmPlus 25cm x 20cm
306003GGZSME	8030413103588	SoFilmPlus 50cm x 35cm
306004GGZSME	8030413103625	SoFilmPlus 50cm x 45cm
306005GGZSME	8030413103687	SoFilmPlus 65cm x 45cm
306006GGZSME	8030413103793	SoFilmPlus 65cm x 60cm
306007GGZSME	8030413103731	SoFilmPlus 95cm x 65cm
306011GGZSME	8030413181036	SoFilmPlus 65cm x 85cm

12 poz

2.7. Packaging

Primary packaging (pouch, sterile barrier)

Film dimension	Pouch dimensions	Content per pouch	Weight per pouch
25cm x 20cm	32cm x 10cm	1 piece	17 grams
50cm x 35cm	45cm x 10cm	1 piece	44 grams
50cm x 45cm	55cm x 10cm	1 piece	56 grams
65cm x 45cm	55cm x 10cm	1 piece	68 grams
65cm x 60cm	75cm x 10cm	1 piece	89 grams
95cm x 65cm	75cm x 10cm	1 piece	132 grams
65cm x 85cm	99cm x 10cm	1 piece	129 grams



įpakavimo pavyzdys

Secondary packaging (inner box)

Film dimension	Inner box dimensions	Content per inner box	Weight per inner box
25cm x 20cm	37cm x 12,5cm x 8cm	10 pouches	0,28 kilograms
50cm x 35cm	57cm x 12,5cm x 8cm	10 pouches	0,59 kilograms
50cm x 45cm	57cm x 12,5cm x 8cm	10 pouches	0,70 kilograms
65cm x 45cm	57cm x 12,5cm x 8cm	10 pouches	0,84 kilograms
65cm x 60cm	74cm x 12,5cm x 8cm	10 pouches	1,09 kilograms
95cm x 65cm	74cm x 12,5cm x 8cm	10 pouches	1,52 kilograms
65cm x 85cm	100cm x 12,5cm x 8cm	10 pouches	1,56 kilograms





Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° **QCT-0146-19**
Certificate no.

Addendum n° **02-19**
addendum no.

Data prima emissione **05.12.2019**
First issue date
 Data di emissione corrente **05.12.2019**
Current issue date
 Data di scadenza **26.05.2024**
Expiry date

DICHIARAZIONE CE DI CONFORMITA' SISTEMA COMPLETO DI GARANZIA DI QUALITA'

secondo l'Allegato II escluso (4) della Direttiva Europea
 93/42/CEE e successive modifiche ed integrazioni.
*(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e
 successive modifiche ed integrazioni)*

EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE SYSTEM

according to Annex II excluding (4) of EC Directive
 93/42/EEC and subsequent modifications and integrations.
*(transposed in Italy by the D.Lgs. n. 46 issued on
 24.02.1997 and subsequent modifications and integrations)*

**L'Istituto Superiore di Sanità,
 Organismo Notificato 0373, certifica che
 il sistema completo di garanzia della qualità
 attuato da**

*The Istituto Superiore di Sanità,
 Notified Body 0373, certifies that
 the total quality assurance system
 enforced by*

MEDIBERG S.r.l.

**Sede Legale/ Registered Office:
 Via Vezze 16/18 – 24050 CALCINATE (BG) ITALIA**

Altre sedi del Fabbrikante /Other sites of the Manufacturer:

Sede Produttiva/ Production Site: Via Vezze 16/18 – 24050 CALCINATE (BG) ITALIA
Sede Operativa/ Operative Office: Via Vezze 16/18 – 24050 CALCINATE (BG) ITALIA

per il dispositivo/i

for the device(s)

*(vedi allegato tecnico/ see technical sheet)**

**è conforme ai requisiti applicabili della
 Direttiva Europea 93/42/CEE e successive
 modifiche ed integrazioni.**

*is in compliance with the applicable
 requirements of Council Directive 93/42/EEC
 and subsequent modifications and integrations.*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.



Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QCT-0146-19**

Addendum n°
addendum no. **02-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe IIa (Class IIa)

<i>Nome prodotto</i> <i>(Product name)</i>	<i>Codice</i> <i>(Code)</i>
<i>Incision film con antimicrobico, sterile</i>	<i>306bbbyyySww</i>

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

306: indica la famiglia; aaa-bbb: numero progressivo; yyy: identifica il materiale e il confezionamento; S: identifica lo stato di sterilità; S: identifica lo stato di sterilità; ww: identifica la personalizzazione.

Valutazione della conformità: vedi MOD-341-01-01 n° 461/19

Conformity assessment : MOD-341-01-01 n. 461/19

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)