

Urgent Field Safety Notice

Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic (References in Annex 1)

Return of the Medical Device to the manufacturer

Att. Users of above product

May 19th, 2025

Dear Sir or Madam,

B. Braun Surgical, S.A., legal manufacturer of Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic medical device products is voluntary recalling specific references/batches of the above-mentioned products.

Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic are mesh implants for re-inforcement of connective tissue structures. They are meshes of polypropylene containing silver that has been knitted to a thin and elastic shape-stable mesh. After implantation the Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic adapt to the longitudinal and latitudinal expansions taking place in the connective tissue.

The antimicrobial properties of silver ions within Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic are intended to help to reduce the risk of microbial colonization and biofilm formation on the surface of the mesh.

Indications for use

Optilene® Silver Mesh LP: Re-inforcement material in connective tissue weakness:

- For incisional hernia repair and inguinal hernia repair

Optilene® Silver Mesh Elastic: Re-inforcement material in connective tissue weakness:

- For incisional hernia repair and inguinal hernia repair

- For prevention of incisional hernia used as a prophylactic mesh in high-risk patients according to the professional criteria (such as but not limited to: age, nutrition, body mass index, comorbidities, etc.).

Identification of affected medical devices:

Reference name: **Optilene® Silver Mesh LP and Optilene® Silver Mesh Elastic**
(Several references affected, see Annex 1)

Reference and batch number: Detailed list in Annex 1 (all batches supplied to the market)

Description of the medical device deficiency:

During an internal review of on-going stability studies of **Optilene® Silver Mesh LP** and **Optilene® Silver Mesh Elastic**, non-compliant results were reported for silver ion release and antimicrobial activity. These results correspond to samples with cardboard as inner packaging.

Therefore, the antimicrobial properties of the meshes cannot be guaranteed whereas all other properties such as mechanical properties are fulfilled during the shelf life of the product (5 years).

Potential harms associated:

The lower silver ion release during mesh implantation does not have any direct clinical impact in the patient. However, the mesh implanted does not fulfil the intended use of the device regarding the silver release. Consequently, the help to reduce the risk of microbial colonization and biofilm formation on the surface of the mesh cannot be guaranteed.

Actions to be taken:

Users of the device should return/discard the device.

In those patients to whom the device has already been implanted, no additional follow-up is required. If the patient presents any complication, the hospital protocol for such situations should be implemented accordingly.

Other information:

Please identify and quarantine if you still have the listed product in your warehouse.

Please check with your customers if they still have the listed product in their warehouse. If yes, ask them to send the product back to you immediately.

Once you have all affected units for return contact us for the management of the material.

This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

In accordance with the European Regulations, we have reported this incidence to the National Competent Authority (NCA) of the European countries involved.

Please, fill out the attached "FSCA/Recall Confirmation Form" and send the completed form to us by June 19th, 2025.

B. Braun Surgical, S.A.

If you have any questions regarding this safety notification, please contact us at the e-mail: vigilance_CT@bbraun.com.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,



Miguel Ángel Benade
Global Manager of Quality &
Technical Responsible (Spain)
B. Braun Surgical, S.A.



B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel.: 93 586 62 00



Martina Laporte
Quality and Regulatory Affairs Director
CoE OR Supply
B. Braun Surgical, S.A.

Annex 1. List of references and batches involved in FSCA QA 024-25_B Braun Surgical

REFERENCES	DESCRIPTION	BATCH
1265230/1265230UNI	OPTILENE SILVER MESH ELASTIC 15 X 15 CM	121194
1265230/1265230UNI		121195
1265230/1265230UNI		122365
1265230/1265230UNI		122475
1265230/1265230UNI		123341
1265240/1265240UNI	OPTILENE SILVER MESH ELASTIC 10 X 15 CM	123341
1265240/1265240UNI		124292
1265240/1265240UNI		125054
1265250/1265250UNI	OPTILENE SILVER MESH ELASTIC 7,5 X 15 CM	123312
1265250/1265250UNI		124302
1265310/1265310UNI	OPTILENE SILVER MESH LP 15 X 15 CM	121222
1265310/1265310UNI		122073
1265310/1265310UNI		122074
1265310/1265310UNI		122092
1265310/1265310UNI		123395
1265310/1265310UNI		124062
1265310/1265310UNI		124243
1265310/1265310UNI		124302
1265320/1265320UNI	OPTILENE SILVER MESH LP 10 X 15 CM	123351
1265320/1265320UNI		123455
1265320/1265320UNI		124184
1265320/1265320UNI		124204
1265320/1265320UNI		124235
1265320/1265320UNI		124253
1265320/1265320UNI		124265
1265320/1265320UNI		124464
1265330/1265330UNI	OPTILENE SILVER MESH LP 7,5 X 15 CM	123354
1265330/1265330UNI		123404
1265330/1265330UNI		124253
1265340/1265340UNI	OPTILENE SILVER MESH LP HOLE/TAIL 6X14CM	120301
1265340/1265340UNI		121222
1265340/1265340UNI		123425
1265340/1265340UNI		124191
1265340/1265340UNI		124283
1265350/1265350UNI	OPTILENE SILVER MESH LP 5 X 10 CM	123354
1265350/1265350UNI		124243
1265360/1265360UNI	OPTILENE SILVER MESH LP HOLE/TAIL 4,5X10CM	123354

Annex 2: Product Identification

Please refer to the representative sample pictures below to identify the references and batches by using the packaging labels.

Individual unit
Optilene® Silver Mesh LP

Reference number

Batch number

Optilene® Silver Mesh LP

B | BRAUN

GB Polypropylene mesh, with Silver, non-absorbable
HR Polipropilenska mrežica sa srebrom. neresorptivna
CZ Polypropylenová síťka se stříbrem, nevstřebatelná
NL Polypropyleen gaas met zilver, niet-absorbeerbaar
EE Polüpropüleenvõrk hõbedaga, mitteabsorbeeruv
FI Hopeoitu polypropyleeniverkko, ei-absorboituva
FR Maille en polypropylène avec argent, non absorbable
DE Polypropylen-Netz mit Silber, nicht resorbierbar
HU Polipropilén háló ezüsttel, nem felszívódó
IT Rete in polipropilene con argento, non assorbibile

LV Polipropilēna tīkls ar sudrabu, neabsorbējošs
LT Polipropileno tinklėlis su sidabru, nesirezorbuojantis
NO Polypropylen-nett med sølv, ikke-absorberbar
PL Siatka polipropylenowa ze srebrem, niewchłaniałna
PT Rede de polipropileno com prata, não absorvível
SK Polypropylénová sieťka obsahujúca striebro, nevstrebateľná
SI Polipropilenska mrežica s srebrom, neabsorptivna
ES Malla de polipropileno con plata, no absorbible
SE Polypropylennät med silver, icke-absorberbart

REF 1265310 36 g/m² LOT 125173 2030-04-23

Pore Shape Ag⁺

15 cm x 15 cm 2025-04-23

B | BRAUN B. Braun Surgical, S.A. Rubí, Spain

Rx Only STERILE EO 0123

503559

Optilene® Silver Mesh Elastic

Reference number

Batch number

Optilene® Silver Mesh Elastic

B | BRAUN

GB Polypropylene mesh, with Silver, non-absorbable
HR Polipropilenska mrežica sa srebrom. neresorptivna
CZ Polypropylenová síťka se stříbrem, nevstřebatelná
NL Polypropyleen gaas met zilver, niet-absorbeerbaar
EE Polüpropüleenvõrk hõbedaga, mitteabsorbeeruv
FI Hopeoitu polypropyleeniverkko, ei-absorboituva
FR Maille en polypropylène avec argent, non absorbable
DE Polypropylen-Netz mit Silber, nicht resorbierbar
HU Polipropilén háló ezüsttel, nem felszívódó
IT Rete in polipropilene con argento, non assorbibile

LV Polipropilēna tīkls ar sudrabu, neabsorbējošs
LT Polipropileno tinklėlis su sidabru, nesirezorbuojantis
NO Polypropylen-nett med sølv, ikke-absorberbar
PL Siatka polipropylenowa ze srebrem, niewchłaniałna
PT Rede de polipropileno com prata, não absorvível
SK Polypropylénová sieťka obsahujúca striebro, nevstrebateľná
SI Polipropilenska mrežica s srebrom, neabsorptivna
ES Malla de polipropileno con plata, no absorbible
SE Polypropylennät med silver, icke-absorberbart

REF 1265250 48 g/m² LOT 125173 2030-04-23

Pore Shape Ag⁺

7,5 cm x 15 cm 2025-04-23

B | BRAUN B. Braun Surgical, S.A. Rubí, Spain

Rx Only STERILE EO 0123

503560

Box
Optilene® Silver Mesh LP

Optilene® Silver Mesh LP

B | BRAUN

GB

Polypropylene mesh, with Silver, non-absorbable

HR

Polipropilenska mrežica sa srebrom, neresorptivna

CZ

Polypropylenová síťka se stříbrem, nevstřebatelná

NL

Polypropylen gaas met zilver, niet-absorbeerbaar

EE

Polüpropüleenvõrk hõbedaga, mitteabsorbeeruv

FI

Hopeoitu polypropyleeniverkko, ei-absorboituva

FR

Maille en polypropylène avec argent, non absorbable

DE

Polypropylen-Netz mit Silber, nicht resorbierbar

HU

Polipropilén háló ezüsttel, nem felszívódó

IT

Rete in polipropilene con argento, non assorbibile

LV

Polipropilēna tīkls ar sudrabu, neabsorbējošs

LT

Polipropileno tinklėlis su sidabru, nesirezorbuojantis

NO

Polypropylen-nett med sølv, ikke-absorberbar

PL

Siatka polipropylenowa ze srebrem, niewchłaniałna

PT

Rede de polipropileno com prata, não absorvível

SK

Polypropylénová sieťka obsahujúca striebro, nevstrebateľná

SI

Polipropilenska mrežica s srebrom, neabsorptivna

ES

Malla de polipropileno con plata, no absorbible

SE

Polypropylennät med silver, icke-absorberbart

REF

1265310

Units: 5

LOT

125173

2030-04-23

Pore

Shape

Ag⁺

15 cm x 15 cm

B | BRAUN

B. Braun Surgical, S.A.
Ctra. de Terrassa, 121
08191 Rubí, Spain.

2025-04-23

STERILE EO

CE

0123

503 557

502

Optilene® Silver Mesh LP

Polypropylene mesh with Silver, non-absorbable

36 g/m²

REF

1265310

LOT

125173

Units: 5

2030-04-23

Ag⁺

15 cm x 15 cm

Reference
number

Batch
number

B. Braun Surgical, S.A._FSN_FSCA QA 024-25

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Box
Optilene® Silver Mesh Elastic

Optilene® Silver Mesh Elastic

Polypropylene mesh, with Silver, non-absorbable

B | BRAUN

(GB) Polypropylene mesh, with Silver, non-absorbable
 (HR) Polipropilenska mrežica sa srebrom, neresorptivna
 (CZ) Polypropylenová síťka se stříbrem, nevstřebatelná
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(LV) Polipropilēna tīkls ar sudrabu, neabsorbējošs
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 (SK) Polypropylénová sieťka obsahujúca striebro, nevstrebateľná
 (SI) Polipropilenska mrežica s srebrom, neabsorptivna
 (ES) Malla de polipropileno con plata, no absorbible
 (SE) Polypropylennät med silver, icke-absorberbart

REF: **1265250**

Units: 5

LOT: **125173**

2030-04-23

Pore Shape



Ag⁺

7,5 cm x 15 cm



(01)04048955176274



(17)300423(10)125173



B | BRAUN

B. Braun Surgical, S.A.
Ctra. de Terrassa, 121
08191 Rubí, Spain.

2025-04-23

STERILE EO

0123

Optilene® Silver Mesh Elastic

Polypropylene mesh with Silver, non-absorbable

B | BRAUN

REF: **1265250**

Units: 5

LOT: **125173**

2030-04-23

Ag⁺

7,5 cm x 15 cm

48 g/m²

0123