



#### SURGICAL SPONGES X-RAY DETECTABLE, GAUZE

**DE** Operationstopfer (mit Röko)  
**FR** Tampons chirurgicaux, radiodéetectables  
**SV** Operationstork med röntgenråd  
**FI** Leikkaussykerö, röntgenlangallinen  
**DA** Operationstampon med röntgenråd  
**NO** Operasjonstopfer med röntgenråd  
**ET** Operatsioonitups, rõ- kontrastne  
**LV** Kirurgiskie tamponi ar rentgenjūtīgu diegu  
**LT** Chirurginiai tamponai, rentgenokonstrastiniai  
**PL** Serwety chirurgiczne, wykrywalne w RTG  
**CS** Chirurgické tampóny, s RTG nítí  
**SK** Chirurgické tampóny, s RTG vláknom  
**ES** Compresa cirurgica com hilo de contraste radiológico  
**PT** Compressa Cirurgica C/ RX  
**NL** Chirurgische sponzen röntgen-detecteerbaar

REF	Diameter	Pack count
3101-01	18 mm	5
3102-01	26 mm	5
3103-01	30 mm	5
3104-01	35 mm	5
3105-01	55 mm	5
3106-01	28 mm	5



#### SURGICAL SWAB X-RAY DETECTABLE, GAUZE

**DE** Kompressen, Röntgenkontrastfaden  
**FR** Compresses chirurgicaux, radiodéetectables  
**SV** Operationskompres med röntgenråd  
**FI** Leikkaustaitos, röntgenlangallinen  
**DA** Operationsserviet med röntgenråd  
**NO** Operationskompres med röntgenråd  
**ET** Operatsioonitampoon, rõ- kontrastne  
**LV** Kirurgiskās salvetes ar rentgenjūtīgu diegu  
**LT** Chirurginiai tvarsčiai, rentgenokonstrastiniai  
**PL** Kompresy włókninowe, wykrywalne w RTG  
**CS** Chirurgické kompresy, s RTG nítí  
**SK** Chirurgické kompresy, s RTG vláknom  
**ES** Compresa com hilo de contraste radiológico  
**PT** Compressa C/ RX  
**NL** Chirurgisch kompres, röntgen detecteerbaar

REF	Size, cm	Ply	Pack count
3206-01	10x10	12	5
3213-01	10x60	4	5
3214-01	10x60	8	5
3215-01	10x60	12	5



#### SURGICAL SWAB X-RAY DETECTABLE, GAUZE

**DE** Operationskompressen aus Röntgenkontrast-Mull, genäht  
**FR** Compresses chirurgicales de gaze détectable aux rayons X, cousues  
**SV** Operationsdukt, gasväv med röntgenråd, sydd  
**FI** Kirurginen taitos harsoa, rög-lanka, ommeltu  
**DA** Kirurgisk gazeserviet med röntgenråd, syet  
**NO** Operasjonsduk med röntgenråd, gasvev  
**ET** Röntgeniga tuvastavast marlist kirurgiline tampoon, õmmeldud  
**LV** Kirurgiska tampona rentgenstaru nosakāmā marle, šūta  
**LT** Chirurginis tamponas iš rentgeno spinduliais aptinkamos marlės, siūtas  
**PL** Wacik chirurgiczny sztyt z gazy wykrywalnej w promieniowaniu rentgenowskim  
**CS** Chirurgické kompresy, s RTG nítí, šité  
**SK** Chirurgický gázový tampón detekovatelný röntgenom, šitý  
**ES** Gasa quirúrgica detectable de hisopo para rayos X, cosida  
**PT** Gaze detetável em raio-X para exsudado cirúrgico, com costura  
**NL** Chirurgisch kompres met röntgencontrastdraad, genaaid

REF	Size, cm	Ply, sewn	Pack count
3217-01	10x60	4	5
3218-01	10x60	8	5
3219-01	10x60	12	5
3220-01	10x10	12	5



#### ABDOMINAL SWAB X-RAY DETECTABLE, GAUZE

**DE** Bauchtücher mit Röntgenkontrastfaden  
**FR** Compresses abdominales, radiodéetectables  
**SV** OP-duk, röntgenråd  
**FI** Keittosuolaliina, röntgenlangallinen  
**DA** Operationskompres med röntgenråd  
**NO** Operasjonsduk med röntgenråd  
**ET** Kõhutampoon, rõ- kontrastne  
**LV** Abdominālās salvetes ar rentgen-jūtīgu diegu  
**LT** Abdominaliniai tvarsčiai, rentgenokonstrastiniai  
**PL** Serwety gazowe z nitką RTG  
**CS** Břišní roušky, s RTG nítí  
**SK** Brušné rúško, s RTG vláknom  
**ES** Compresa com hilo de contraste radiológico  
**PT** Compressa Abdominal C/ RX  
**NL** Abdominaal kompres met röntgencontrastdraad

REF	Size	Pack count
3310-01	30x45	5
3311-01	45x70	1
3312-01	45x70	5
3316-01	40x45	5

#### Intended Purpose:

evercare® X-ray detectable swabs and sponges, gauze are sterile single-use surgical swabs and sponges, made from woven gauze and containing an x-ray detectable thread, primarily intended to be used inside the body, on a surgical incision or applied to internal organs or structures to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, contamination during a procedure. Intended User is a Health Care Professional.

#### Indications:

The products principle of operation is primarily absorption of body fluids, creating a mechanical barrier when used to protect organs from abrasion and contamination during surgical procedures. The round shaped sponge may also be used to generate a friction when the device is used for dissection of soft tissues. The devices are featured with coloured X-ray opaque thread to be fully X-ray detectable while in the patient's body. The evercare® X-ray detectable swabs and sponges, gauze are designated to be soft, low linting and highly fluid absorbing.

#### Instruction for use:

The evercare® X-ray detectable swabs and sponges, gauze, sterile are single-use devices intended to be used in health-care settings in the operating theater by health care professionals educated and experienced in surgery or in non-surgical medical fields where the tamponades are used.

- Use the aseptic technique to open the primary packaging starting from the directions indicated on the pouch paper side.
- Take out the content and place it on a sterile surface.
- Control the items amount in the inner pouch. The number of items shall be equal to the quantity stated on the product label and the control label (where applicable).
- Peel off one control label (where applicable) from the inner pouch and add it to the patient's protocol. Peel off another control label and paste on a collecting bag/container intended for discarded devices after usage.
- Use the device in the surgical wound according to the internal surgical procedure.

#### Contraindications:

No known contraindications for the evercare® X-ray detectable swabs and sponges, gauze, sterile.

#### Warning:

In case of discrepancy between the counted number of items inside the primary packaging and the quantity

stated on the packaging label or control label, do not use the device and discard it as the number of used items can not be traced.

Do not use the device if package is damaged as the sterility state would be altered.

The device is for single use only. Re-use would cause product integrity and wound contamination.

Do not re-sterilize the device. The device properties would be altered.

Do not use the product after the expiration date. If used after exp. date product's properties cannot be ensured.

#### Removal and Disposal:

- Remove all used items from the wound and dispose according to the local disposal regulation.
- Device with control label:
  - o Remove all used items from the wound and place them on the site where item amount counting can be done.
  - o Counting of used items: Count the number of used items outside the wound before final skin stitching. Quantity of used items outside the wound shall be equal to the quantity stated on the control label for the device. If the quantities are not equal, inspect the wound again. If the discrepancy in the quantities remains, the X-ray screening of the wound shall be performed to identified remained device(s) in the wound.
- Dispose the product according to the local regulation for biologically contaminated waste.

#### Storage:

The devices are packed in three-layers packaging. Store the devices in their original packaging in a cool, dry and clean space.

#### Notice:

Serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

These instructions for use were drawn up in English and have been translated into other languages. In the event of inconsistencies of interpretations, the English text shall be determinative.



#### Single sterile barrier system

**fr** Système de barrière stérile unique  
**de** Einfaches steriles Barriersystem  
**sv** Enkelt sterilbarriärsystem  
**fi** Yksinkertainen steriili suojajärjestelmä  
**da** Enkelt steril barriersystem  
**no** Enkelt steril barriersystem  
**et** Ühekordne steriilne tõkkesüsteem  
**lv** Vienas sterīlas barjeras sistēma  
**lt** Vieno sterilaus sluoksnio sistema  
**pl** System pojedynczej bariery sterylnej  
**sk** Jediný sterilný bariérový systém  
**cs** Jednotlivý systém sterilní bariéry  
**es** Sistema de barrera estéril único  
**pt** Sistema de barreira única estéril  
**nl** Enkellaags steriel barriërsysteem

#### Single sterile barrier system with protective packaging inside

**fr** Système de barrière stérile unique avec emballage protecteur à l'intérieur  
**de** Einfaches steriles Barriersystem mit Schutzverpackung innen  
**sv** Enkelt sterilbarriärsystem med skyddsförpackning på insidan  
**fi** Yksinkertainen steriili suojajärjestelmä, jossa suojapakkaus sisällä  
**da** Enkelt steril barriersystem med beskyttende emballage indeni  
**no** Enkelt steril barriersystem med beskyttende innvendig emballasje  
**et** Sisaldab kaitsepakendiga ühekordset steriilset tõkkesüsteemi  
**lv** Iekšā ir viena sterīlas barjeras sistēma ar aizsargiekpakojumu  
**lt** Vieno sterilaus sluoksnio sistema su apsaugine pakuote viduje  
**pl** System pojedynczej bariery sterylnej z opakowaniem ochronnym w środku  
**sk** Jediný sterilný bariérový systém s ochranným obalom vnútri  
**cs** Jednotlivý systém sterilní bariéry s ochranným balením uvnitř  
**es** Sistema de barrera estéril único con embalaje protector en el interior  
**pt** Sistema de barreira única estéril com embalagem de proteção no interior  
**nl** Enkellaags steriel barriërsysteem met beschermende verpakking binnenzijde



#### Healthcare professional use

**fr** Utilisation réservée aux professionnels de santé  
**de** Für medizinische Fachkräfte  
**sv** För användning av sjukvårdspersonal  
**fi** terveydenhuollon ammattilaisten käyttöön  
**da** Til brug af sundhedspersonale  
**no** For bruk av helsepersonell  
**et** Ette nähtud kasutamiseks tervishoiutöötajatele  
**lv** Paredzēts lietošanai profesionālā veselības aprūpē  
**lt** Skirta naudoti sveikatos priežiūros specialistams  
**pl** Do użytku profesjonalnego w służbie zdrowia  
**sk** Určené pre zdravotníckych pracovníkov  
**cs** Profesionální použití ve zdravotnictví  
**es** Para uso de profesionales sanitarios  
**pt** Para uso de profissionais de saúde  
**nl** Healthcare professioneel gebruik

#### Not made with natural rubber latex

**fr** Fabriqué sans latex de caoutchouc naturel  
**de** Nicht aus Naturkautschuklatex hergestellt  
**sv** Inte tillverkad av naturgummilåtex  
**fi** Ei sisällä luonnonkumilåteksiä  
**da** Ikke fremstillet med naturgummilåtex  
**no** Inneholder ikke naturgummilåtex  
**et** Ei ole valmistatud looduslikust kummilåteksist  
**lv** Nav izgatavots no dabiskā kaučuka lateksa  
**lt** Pagaminta be natūralios gumos lateksu  
**pl** Nie zawiera naturalnego lateksu  
**sk** Nie je vyrobená z prírodného kaučukového latexu  
**cs** Neobsahuje přírodní kaučuk  
**es** No fabricada con látex de caucho natural  
**pt** Não é feito com látex de borracha natural  
**nl** Niet gemaakt van natuurrubber latex