

## EN OsseoGuard® INSTRUCTIONS FOR USE

**Intended Use:**

*OsseoGuard*® is a bioresorbable, implantable collagen material that is intended for use in periodontal and/or dental surgery procedures as a material for placement in the area of periodontal defects, dental implant, bone defect or ridge reconstruction to aid in wound healing post surgery.

**Description:** *OsseoGuard*® is a white, nonfilable membrane matrix engineered from highly purified type I collagen fibers derived from bovine Achilles tendon. *OsseoGuard*® is resorbable which eliminates the need for a second surgical procedure that is normally required to remove a non-resorbable membrane.

*OsseoGuard*® has a morphology of dense oriented fibers for mechanical strength. Macromolecular permeation studies have shown that the membrane is permeable to macromolecules. Its porosity is such that it effectively retards epithelial down growth and prevents gingiva connective cell migration into the wound site. The semi-permeability properties of the membrane permit the exchange of essential nutrients for wound healing. *OsseoGuard*® is sterilized by gamma irradiation and is for single use only.

**Administration:** *OsseoGuard*® is packaged in a double sterile pouch. The outer pouch should be opened carefully, allowing the inner pouch to be placed onto a sterile field. The membrane should be removed from the inner pouch with sterile gloves or instruments.

The periodontal defect or bone defect is exposed by a mucoperiosteal flap and basic surgical procedures are performed (e.g. curettage). The clinician should perform thorough debridement and good planning of the defect. Space-making material such as autologous bone, demineralized bone matrix and ceramic materials may be used to fill the defect. As much tissue as possible should be preserved to allow for primary closure of the wound and correct positioning of the flaps.

*OsseoGuard*® can be placed either dry or hydrated. If the clinician prefers the handling characteristics of the hydrated collagen, the membrane can be hydrated in sterile water or saline solution for approximately five minutes prior to the final placement.

*OsseoGuard*® can be trimmed to the size and shape of the defect in the dry or wet state using sharp, sterile scissors.

*OsseoGuard*® should overlap the walls of the defect by at least 2mm to allow complete bone contact and to prevent gingival connective tissue invasion below the material.

Fixation of the membrane may be indicated to avoid displacement due to loading or mobilization. The membrane can be sutured in place using absorbable sutures or a non-cutting needle. Resorbable tacks can also be used to affix the membrane. The mucoperiosteal flap is sutured over the collagen membrane and the wound should be closed completely to avoid accelerated resorption due to membrane exposure.

**Post-operative Procedures:** *OsseoGuard*® is completely resorbable and should not be removed. Patients should rinse with an antimicrobial agent such as chlorhexidine gluconate (Peridol) twice daily for four weeks following surgery. Beginning 24 hours after surgery, the wound site may be additionally swabbed with a cotton-tipped applicator dipped in the antimicrobial agent.

*OsseoGuard*® is fully absorbent and resorbable over a 26 to 38 week period. Patient self hygiene and antimicrobial mouth rinses will continue to be necessary for the duration of the resorption period.

The patient should refrain from brushing the treated area for two weeks following the surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Dental floss should not be used prior to four weeks following surgery. Coronal scaling and prophylaxis can be performed at follow-up visits, if indicated.

The patient should be seen seven to ten days following surgery for wound evaluation and removal of any dosing sutures or periodontal packing. These follow-up visits should be repeated every two weeks thereafter, up to eight weeks following surgery. The patient may return to normal oral hygiene routine.

*OsseoGuard*® should be completely resorbed 26 to 38 weeks following surgery. However, probing and subgingival scaling should not be performed prior to six months following surgery to prevent damage to immature tissues. Other assessments of clinical health may be repeated, including plaque, bleeding and tooth mobility indices.

**Contraindications:**

*OsseoGuard*® is contraindicated in patients who have:

- acute infections or contaminated wound in the oral cavity
- known allergy to collagen of animal origin or other bovine-derived products
- clinically significant renal, hepatic, cardiac, endocrine, hematologic, autoimmune or systemic disease, which in the physician's judgment, will prevent safe implantation or likely healing.

**Warning:**

Clinicians should use care in screening their patients for any known allergies to collagen or bovine-derived products. Hypersensitivity reactions have been noted with the use of other products containing bovine collagen; therefore, the possibility exists of developing a local sensitivity response to *OsseoGuard*®.

**Precautions:**

As with all surgical procedures, caution should be exercised when treating medically compromised patients such as patients receiving long-term steroid therapy or currently taking anticoagulants. Patients with clinically significant systemic diseases, indicating a history of anaphylactic reactions, autoimmune diseases, uncontrolled diabetes or severe hypertension have not been implanted with the membrane; therefore, the safety and effectiveness for those patients have not been determined. Nor has it been evaluated in pregnant women, children and/or in patients with conditions involving extremely severe defects with little periodontium or bone. *OsseoGuard*® cannot be re-sterilized. Once, unused *OsseoGuard*® must be discarded. *In vivo* stability may be adversely affected if re-sterilized.

Cross-contamination and infection may occur if re-used. Do not use if the product sterilization barrier or its packaging is compromised.

**Adverse Reactions:**

Possible complications that can occur with any dental surgery include infection, swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis, with loss of crestal bone height, pain, or complications associated with the use of anesthesia. Minor discomfort may occur for a few days.

**Safety:** The product is manufactured from bovine Achilles tendon, which is classified as tissue with no detected infectious agents (Bovine Spongiform Encephalitis/BSE (World Health Organization Guidelines)). The bovine tendon is known to be one of the richest sources of type I collagen that is commercially available.

The manufacturing process for the product meets European Standards and International Standards for animal tissue sourcing, handling and inactivation of Spongiform Encephalopathy (SE) pathogens. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of SE pathogens.

A viral inoculation study for the product's manufacturing process was conducted by an independent laboratory. In this study key manufacturing steps were evaluated for their ability to inactivate the following viral strains: Bovine Viral Diarrhea (enveloped virus) and Porcine Parvovirus (non-enveloped virus). The study results showed that each of the manufacturing steps evaluated, including the sodium hydroxide treatment, is effective in inactivating these viruses.

**Storage:** The product should be stored at room temperature. Avoid excessive heat and humidity. **How Supplied:** One (1) membrane per package, size 1.5 cm x 2.0 cm, 2.0 cm x 3.0 cm, or 3.0 cm x 4.0 cm **Caution:**

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist. **Labeling Symbols:** Symbols may be used on some international package labeling for easy identification. ©2017 Zimmer Biomet. All rights reserved. OsseoGuard is a registered trademark of Zimmer Biomet or its affiliates.

## DA OsseoGuard® BRUGSANVISNING

**Tilgjet anvendelse:** *OsseoGuard*® er et bioresorbabelt og implanterbart kollagenmateriale beregnet til anvendelse ved parodontale og/eller dentalkirurgiske indgreb. Materialet kan placeres i områder med parodontale defekter, dentale implantater, knogledefekter eller rekonstruktion af processus alveolaris som en hjælp til healing af sår postoperativt.

**Beskrivelse:** *OsseoGuard*® er en hvid, ikke-sprød membranmatris fremstillet af højtporøse type I kollagenfibre, der er afflett fra bovine achilles-tendoner. *OsseoGuard*® er resorbabel, hvilket eliminerer behovet for endnu et kirurgisk indgreb, som normalt er nødvendigt for at fjerne en non-resorbabel membran.

*OsseoGuard*® består af tattede fibre, som giver mekanisk styrke. Makromolekylære permeationsstudier har vist, at membranen er permeabel over for makromolekylære næringsstoffer. Disse porer gør den i stand til effektivt at holde epitelceller og vaskulære celler tilbage og forhindre gingival blindevækst eller isigerming ind i såret. Membranens semipermeabilitet giver mulighed for udveksling af de essentielle næringsstoffer, der er nødvendige til sårhealing.

**Administration:** *OsseoGuard*® er pakket i en dobbelt steril pose. Den ydre pose skal åbnes forsigtigt, så den indvendige pose kan bringes på et sterilt felt. Membranen skal tages ud af den indvendige pose med sterile handsker eller instrumenter.

The periodontal defect or bone defect is exposed by a mucoperiosteal flap and basic surgical procedures are performed (e.g. curettage). The clinician should perform thorough debridement and good planning of the defect. Space-making material such as autologous bone, demineralized bone matrix and ceramic materials may be used to fill the defect. As much tissue as possible should be preserved to allow for primary closure of the wound and correct positioning of the flaps.

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**Post-operative Procedures:** *OsseoGuard*® is completely resorbable and should not be removed. Patients should rinse with an antimicrobial agent such as chlorhexidine gluconate (Peridol) twice daily for four weeks following surgery. Beginning 24 hours after surgery, the wound site may be additionally swabbed with a cotton-tipped applicator dipped in the antimicrobial agent.

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A viral inoculation study for the product's manufacturing process was conducted by an independent laboratory. In this study key manufacturing steps were evaluated for their ability to inactivate the following viral strains: Bovine Viral Diarrhea (enveloped virus) and Porcine Parvovirus (non-enveloped virus). The study results showed that each of the manufacturing steps evaluated, including the sodium hydroxide treatment, is effective in inactivating these viruses.

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## DE OsseoGuard® GEBRAUCHSANLEITUNG

**Verwendungszeck:**

*OsseoGuard*® ist ein bioresorbierbares, implantierbares Kollagenmaterial für die Parodontal- bzw. Zahnchirurgie, das in Bereiche mit Parodontaldefekten, Zahnimplantaten, Knochendefekten oder Kammrekonstruktion eingebracht wird, um die Wundheilung nach der Operation zu unterstützen.

**Beschreibung:** *OsseoGuard*® ist eine weiße, nicht brüchige Membranmatrrix, die aus hochgereinigten Typ-I-Kollagenfasern aus bovinen Achillessehnen hergestellt wird. *OsseoGuard*® ist resorbierbar. Ein zweites chirurgisches Eingriff, wie es normalerweise zur Entfernung einer nicht resorbierbaren Membran durchgeführt werden muss, ist daher nicht erforderlich.

*OsseoGuard*® zeichnet sich durch dicht angeordnete Fasern und dadurch hohe mechanische Stärke aus. Makromolekulare Permeationsstudien haben gezeigt, dass die Membran für Makromoleküle durchlässig ist. Die Porosität bewirkt eine Verzögerung des epithelialen Einwachsens und verhindert die Migration gingivalen Bindegewebes in Richtung der Extraktionsfläche. Die semipermeable Membran ermöglicht den Austausch essentieller Nährstoffe für die Wundheilung.

*OsseoGuard*® wird gammasterrilisiert und ist nur zur einmaligen Verwendung vorgesehen.

**Anwendung:**

*OsseoGuard*® wird in einem sterilen Doppelbeutel geliefert. Der äußere Beutel ist vorsichtig so zu öffnen, dass der innere Beutel in das sterile Feld eingebracht werden kann. Die Membran ist mit sterilen Handschuhen oder Instrumenten aus dem inneren Beutel zu entnehmen.

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**Lieferform:** Eine (1) Membran pro Packung, Größe 1,5 cm x 2,0 cm, 2,0 cm x 3,0 cm oder 3,0 cm x 4,0 cm

**Achtung:** In den USA darf dieses Produkt nach den gesetzlichen Vorschriften nur durch einen Arzt oder Zahnarzt abgegeben werden.

**Bildzeichen:** Auf einigen internationalen Verpackungsetiketten werden Symbole zur leichteren Identifizierung verwendet. ©2017 Zimmer Biomet. Alle Rechte vorbehalten.

OsseoGuard ist eine eingetragene Marke von Zimmer Biomet oder damit verbundenen Unternehmen.

## EL OsseoGuard® ΟΑΪΩΣ ΧΡΗΣΗΣ

**Χρήση για την οσία προεγχείρηση:**

Το προϊόν κατασκευάζεται από αγιλίο τένοντα βοοειδών, ο οποίος τζανύεται ως ιστός χωρίς ανοχή στην επεξεργασία με υδροξείδιο του νατρίου, η οποία είναι μια αναγνωρισμένη μέθοδος αποστείρωσης των παθόντων της ΣΕ.

Από ένα ανεξάρτητο εργαστήριο διενεργήθηκε μελέτη κατάφ ανδροποίησης για τη διεργασία παρασκευής του προϊόντος. Στη μελέτη αυτή ελεγχόθησαν για τη βιωσιμότητα παθόντων για την ακριβήτωση τους ανδροποίησης των ισθών των ισθών, οι οποίοι ελεγχθησαν ως διάφοροι βοοειδών (εγκυμωμένοι ισθί) και Παρωνεζία χοίρων (για εγκυμωμένους ισθί). Τα αποτελέσματα της μελέτης έδειξαν ότι καθένα από τα βήματα παρασκευής συμπεριλαμβανομένης της επεξεργασίας με υδροξείδιο του νατρίου, είναι αποτελεσματικό στην ανδροποίηση των ισθών.

**Θυλάκι:** Το προϊόν πρέπει να φυλάσσεται σε θερμοκρασία δωμάτιου. Αποφεύγεται την υπερβολική θερμότητα και υγρασία.

**Τρόπος διάθεσης:** Μία (1) μεμβράνη ανά συσκευασία, μέγεθος 1,5 cm x 2,0 cm, 2,0 cm x 3,0 cm ή 3,0 cm x 4,0 cm

**Προσοχή:** Η ορμονογόνα νορθεσία (των Η.Π.Α.) περιέχει την μάληξη της σκουσικής αυτής μόνον από ισθό ή οδοντοίτη ή καπνό ενοχλής τούης.

**Σύμβολο ενδοκίνησης:** Σε κάποιο δείκτη επισημάνουν συσκευασίες μπει να χρησιμοποιούνται σύμβολα για εύκολη αναγνώριση. ©2017 Zimmer Biomet. Όλα τα δικαιώματα κρατούνται.

OsseoGuard είναι κατοχυρωμένο σήμα της Zimmer Biomet ή των θυγατρικών της.

**Asloeg:**

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Από ένα ανεξάρτητο εργαστήριο διενεργήθηκε μελέτη κατάφ ανδροποίησης για τη διεργασία παρασκευής του προϊόντος. Στη μελέτη αυτή ελεγχόθησαν για τη βιωσιμότητα παθόντων για την ακριβήτωση τους ανδροποίησης των ισθών των ισθών, οι οποίοι ελεγχθησαν ως διάφοροι βοοειδών (εγκυμωμένοι ισθί) και Παρωνεζία χοίρων (για εγκυμωμένους ισθί). Τα αποτελέσματα της μελέτης έδειξαν ότι καθένα από τα βήματα παρασκευής συμπεριλαμβανομένης της επεξεργασίας με υδροξείδιο του νατρίου, είναι αποτελεσματικό στην ανδροποίηση των ισθών.

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## ES OsseoGuard® INSTRUCCIONES DE USO

**Indicaciones:** *OsseoGuard*® es un material de colágeno implantable bioabsorbible indicado para utilizarse en intervenciones quirúrgicas periodontales o dentales que se coloca en defectos periodontales, implantes dentales, defectos óseos o reconstrucciones crestales para fomentar la cicatrización postquirúrgica de la herida.

**Descripción:** *OsseoGuard*® es una matriz de membrana no fríasle de color blanco elaborada a partir de fibras de colágeno tipo I altamente purificadas obtenidas a partir de tendón de Achilles bovino. *OsseoGuard*® es resorbible, lo que elimina la necesidad de una segunda intervención quirúrgica requerida normalmente para extraer las membranas no resorbibles.

*OsseoGuard*® tiene una morfología de fibras densas orientadas para ofrecer resistencia mecánica. Los estudios de permeabilidad macromolecular han demostrado que la membrana es permeable a las macromoléculas. Sus porosidad retarda eficazmente el crecimiento epitelial descendiente y evita la migración de células conjuntivas gingivales al interior del lugar quirúrgico. Las propiedades semipermeables de la membrana permiten el intercambio de nutrientes esenciales para la cicatrización de la herida.

*OsseoGuard*® está esterilizada con radiación gamma y es para un solo uso.

**Administración:** *OsseoGuard*® es presentado en una bolsa estéril doble. La bolsa exterior debe abrirse con cuidado para facilitar la colocación de la bolsa interior en un campo estéril. La membrana debe extraerse de la bolsa interior con guantes o instrumentos estériles.

El defecto periodontal o el defecto óseo se dejan al descubierto mediante un colgajo mucoperiosteico, tras lo que se realizan los procedimientos quirúrgicos básicos (p.ej., legrado). El clinico debe llevar a cabo un desbridamiento cuidadoso y un buen aplanchamiento del defecto. Para relajar el defecto puede utilizarse material espaciador, como hueso autólogo, matriz ósea desmineralizada o materiales cerámicos. Deve conservarse tanto tejido como sea posible para poder llevar a cabo el cierre primario de la herida y la colocación correcta de los colgajos.

*OsseoGuard*® se esteriliza con radiación gamma y es para un solo uso.

**Administración:** *OsseoGuard*® es presentado en una bolsa estéril doble. La bolsa exterior debe abrirse con cuidado para facilitar la colocación de la bolsa interior en un campo estéril. La membrana debe extraerse de la bolsa interior con guantes o instrumentos estériles.

El defecto periodontal o el defecto óseo se dejan al descubierto mediante un colgajo mucoperiosteico, tras lo que se realizan los procedimientos quirúrgicos básicos (p.ej., legrado). El clinico debe llevar a cabo un desbridamiento cuidadoso y un buen aplanchamiento del defecto. Para relajar el defecto puede utilizarse material espaciador, como hueso autólogo, matriz ósea desmineralizada o materiales cerámicos. Deve conservarse tanto tejido como sea posible para poder llevar a cabo el cierre primario de la herida y la colocación correcta de los colgajos.

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