

SINGLE USE BIRD CUP

SINGLE USE BIRD CUP

EINWEG
BIRD SAUGGLOCKEVENTOUSE
A USAGE UNIQUE BIRDVENTOSA
OSTETRICA MONOUSOVACÜM-CUP VOOR
EENMALIG GEBRUIKBIRD CUP
FÖR ENGÅNGSBRUK

BIRD ENGANGSSUGEKOP



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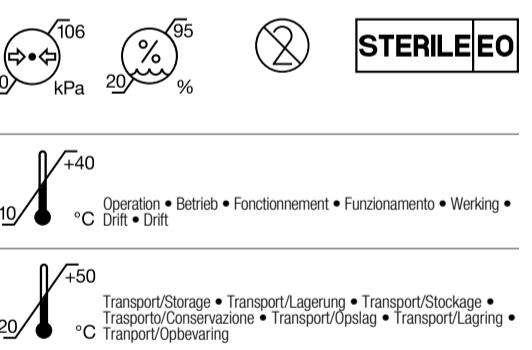
NL Veiligheidsvoorschriften

ALLMÄN INFORMATION

SV Säkerhetsföreskrifter

GENERELT

DA Sikkerhedsforskrifter



STERILE EO

CE 0123
Made in Switzerland

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This obstetrical instrument is utilized to assist a clinician in the delivery of an infant during childbirth.

Important note
Proper surgical procedures and techniques are the responsibility of the medical practitioner. Each physician must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

General information
The Single Use Bird Cup is made in four pieces: The cup consists of Polycarbonate and inside the cup is a bottom plate mesh. The traction handle is made of Nylon and the locking piece consists of ABS Plastic. The mesh enables the air between the cup and the child's head to be evacuated and ensure that the cup sucks firmly against the child's head.

Pump requirements
• This obstetrical instrument has been developed for use in conjunction with an external vacuum source capable of precise vacuum regulation to ensure proper vacuum levels (up to -80 kPa/-600 mmHg).
• We recommend using the Medela Basic suction pump.
• The vacuum source should be designed for medical purposes and may be either electric or manual.
• Note: Wall suction is not to be used.

Tubing requirements
The tubing connecting the instrument to the vacuum source is vital for safe and proper function of the instrument. To ensure this only Medela original tubing should be used.

Anforderungen an die Pumpe
• Dieses Instrument zur Geburtshilfe ist für die Anwendung mit einer externen Vakuumquelle mit präziser Vakuumregelung zur Bewahrung der angemessenen Vakuumstärke (bis -80 kPa/-600 mmHg) ausgelegt.
• Wir empfehlen die Verwendung der Medela Basic Absaugpumpe.
• Die Vakuumsquelle sollte für medizinische Zwecke bestimmt sein und kann elektrisch oder manuell betrieben werden.
• Hinweis: Zentralvakuum darf nicht verwendet werden.

Safety rules
• Do not use if:
– The product has exceeded the expiration date on the packaging.
– Packaging is opened or damaged.
– If the device is damaged.
– If the device shows clear safety defects.
• Wall suction is not to be used.
• Vacuum extraction must only be performed or supervised by trained and experienced clinicians.
• The neonatal care staff must be aware of the indications, contraindications and precautions for assisted delivery and must watch for the signs of complications of vacuum assisted delivery.

• Operative vaginal delivery should not be performed when the probability of success is very low.
• Ensure against intrusion of extraneous tissues and ensure proper placement of cup.
• Attention: Never apply the cup to any portion of the infant's face as this can cause fetal trauma.

• Insertion should be performed carefully to avoid malfunctions, maternal or fetal trauma and maternal discomfort.
• The head, not just the scalp, must descend with each pull.
• Pull only during a contraction.

• Always apply traction at an angle allowing the stem of the cup to remain in-line or on-axis.
• Never apply rocking movements or torque to the device, only steady traction should be used.

• Discontinue vacuum extraction if there is evidence of significant scalp trauma or damage.
• The head must be delivered, or almost completely delivered, with no more than three pulls.

• The head must be completely delivered within 15–20 minutes of first applying the cup.
• Never exceed 10 minutes of cumulative traction time.

• Never exceed maximum recommended vacuum -80 kPa (-600 mmHg) or "pop off" (2) – scalp trauma can occur.

• Discontinue vacuum extraction if the vacuum cup becomes disengaged or pops off twice.
• Do not pull three times, if the second pull fails to produce good descent.

• Parents should be instructed to check the baby's health.
• The infant has to be watched for several days for possible problems.

Disposal
Single use only. After use, dispose of according to local regulations.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Dieses Instrument zur Geburtshilfe wird verwendet, um den Arzt bei der Geburt eines Babys zu unterstützen.

Wichtiger Hinweis
Die Befoligung ordnungsgemäßer chirurgischer Verfahrensweisen und Techniken liegt in der Verantwortung des Arztes. Jeder Arzt muss die jeweilige Angemessenheit des Verfahrens nach eigenem Wissen und eigener Erfahrung beurteilen.

Allgemeine Informationen
Die Einweg Bird Saugglocke besteht aus 4 Teilen: Die Glocke ist aus Polycarbonat. Darin enthalten ist eine Netzeinlage. Der Zugriff ist aus Nylon und die Verbindung zur Saugglocke aus ABS Kunststoff. Die Funktion der Netzeinlage besteht darin, den Sog gleichmässig zwischen Kopf des Kindes und Saugglocke zu verteilen, damit die Saugglocke durch Saugkraft fest am Kopf des Kindes haftet.

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• Wir empfehlen die Verwendung der Medela Basic Absaugpumpe.
• Die Vakuumsquelle sollte für medizinische Zwecke bestimmt sein und kann elektrisch oder manuell betrieben werden.
• Hinweis: Zentralvakuum darf nicht verwendet werden.

Sicherheitsregeln
• Nicht verwenden wenn:
– Das Produkt das Ablaufdatum überschritten hat.
– Die Verpackung offen oder beschädigt ist.
– Das Instrument beschädigt ist.
– Das Instrument offensichtliche Sicherheitsmängel aufweist.
• Zentralvakuum darf nicht verwendet werden.

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• Ensure against intrusion of extraneous tissues and ensure proper placement of cup.
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Entsorgung
Nur zum einmaligen Gebrauch. Nach Benutzung gemäss lokalen Vorschriften entsorgen.

VENTOUSE
A USAGE UNIQUE BIRD

La ventouse obstétricale, est un instrument utilisé lors de l'accouchement pour faciliter l'expulsion.

Note importante
Le praticien qualifié est responsable des procédures et interventions chirurgicales appropriées à chaque patiente. Il incombe à chaque médecin d'évaluer la convenance des procédures à appliquer, en fonction de sa formation et son expérience individuelle.

Généralités
La ventouse unique Bird est composée de 4 parties: la cuvette, qui est en polycarbonate et contient au fond un diaphragme perforé. La poignée de traction est en nylon et la pièce de connexion en plastique ABS. Le diaphragme permet l'évacuation de l'air entre la ventouse et la tête de l'enfant, et assure une bonne adhérence entre les deux parties.

Exigences concernant l'aspirateur médical
• La ventouse obstétricale doit être utilisée avec une source de vide externe adaptée pour assurer le raccordement et le maintien de niveaux de pression suffisants (jusqu'à -80 kPa/-600 mmHg).
• Nous recommandons l'utilisation de l'aspirateur Medela Basic.
• La source de vide doit être spécialement conçue pour l'usage médical et doit être électrique ou manuelle.
• Note: Ne pas utiliser le vide central comme source de vide

Spécifications du tuyau
Le tuyau qui relie la ventouse à usage unique à la source de vide est un élément essentiel pour le fonctionnement correct et sans risque de l'instrument. Pour garantir ces spécifications, n'utiliser qu'un tuyau Medela original.

Règles de sécurité
• Ne pas utiliser si:
– Le produit a dépassé la date de péremption inscrite sur l'emballage.
– La conception est ouverte ou dénigrée.
– L'emballage est ouvert ou endommagé.
– L'instrument est endommagé.
– L'instrument montre des défauts évidents.
• Ne pas utiliser le vide central.

• L'extraction sous vide ne doit pas être effectuée ou supervisée que par des médecins spécialement formés et expérimentés.

• Le personnel soignant du nouveau-né doit connaître les indications, contre-indications et mesures de sécurité relatives à l'extraction sous vide et savoir reconnaître les complications survenant pendant son utilisation.

• L'estraction avec vuoto può essere eseguita o controllata solo da medici esperti e addestrati.

• Il personale di cura neonatale deve conoscere le indicazioni, contro-indicazioni e le precauzioni relative al parto assistito nel parto assistito con il vuoto.

• Il parto operativo vaginale non dovrebbe essere eseguito se la probabilità di successo è molto bassa.

• Assicurarsi che non entri alcun tessuto estraneo e che la ventosa sia nella giusta posizione.

• Attenzione: non posizionare mai la ventosa sul viso del bambino poiché ciò può causare un trauma fetale.

• La ventosa dovrebbe essere inserita con molta cura per evitare malfunzionamenti, traumi alla madre o al feto e disagi alla madre.

• In ogni trazione deve scendere la testa, non solo il cuoio capelluto.

• Tirare solo durante una contrazione.

• Tirare sempre con un'angolatura tale che permetta di evitare il trauma materno o fetale, e di impedire dei dolori alla madre.

• C'è la testa, e poi solo il cuoio capelluto.

• Nella trazione deve scendere la testa, non solo il cuoio capelluto.

• Tirare solo durante una contrazione.

• Tirare sempre con un'angolatura tale che permetta di evitare il trauma materno o fetale.

• La testa deve essere estratta completamente entro 15–20 minuti dalla prima applicazione della ventosa.

• Non superare mai 10 minuti di tempo totale di trazione.

• Mai superare il vuoto massimo consigliato di -80 kPa (-600 mmHg) o il numero di distacchi della ventosa (2x).

• Non possono avere lesioni alla testa.

• Interrompere l'estrazione con vuoto se la ventosa si stacca più di due volte.

• Non esercitare la terza trazione, se la seconda non produce una discesa evidente.

• I genitori devono essere istruiti su come controllare la salute del bambino.

• Il bambino deve essere osservato per diversi giorni per evidenziare eventuali problemi.

Smaltimento
Monuso. Smaltire dopo l'uso rispettando le norme locali.

Elimination
Usage unique. Après usage, éliminer conformément aux prescriptions locales en vigueur.

VENTOSA
OSTETRICA MONOUSO

Questo strumento ostetrico viene usato per aiutare il medico durante il parto

Nota importante
E' responsabilità del medico adottare le procedure e le tecniche chirurgiche appropriate. Ogni medico deve valutare l'idoneità della procedura in base alla propria formazione ed esperienza clinica.

Informazioni generali
La ventosa ostetrica monouso Medela è formata da 4 parti: la ventosa è in policarbonato. All'interno è contenuta una placca di fondo a rete. L'impugnatura di trazione è in nylon e la pezzo di collegamento alla ventosa è in plastica ABS. La poignée permet l'évacuation de l'air entre la ventouse et la tête de l'enfant, et assure une bonne tenuta della ventosa sulla testa del bambino.

Requisiti dell'aspiratore
• Questo strumento ostetrico deve essere utilizzato con una sorgente di vuoto esterna ad alta precisione per assicurare il raggiungimento e il mantenimento di livelli di depressione adeguati (fino a -80 kPa/-600 mmHg).
• Raccomandiamo l'impiego della pompa aspirante Medela Basic.
• La sorgente di vuoto deve essere destinata specificamente ad applicazioni mediche e può essere sia elettrica che manuale.
• Nota: Non utilizzare un aspiratore a muro (vuoto centralizzato).

Eisen voor slangen
De slang die de Bird Cup voor eenmalig gebruik op de vacuümbron aansluiten zijn essentieel voor het veilig en goed functioneren van het instrument. Om dit te verzekeren dienen alleen oorspronkelijke Medela slangen te worden gebruikt.

Requisitos dei tubi
I tubi che collegano lo strumento monouso alla sorgente del vuoto sono essenziali per il funzionamento sicuro e corretto dello strumento. A tal fine, si devono usare solo tubi originali Medela.

Norme di sicurezza
• Da non usare se:
– Il prodotto ha superato la data di scadenza riportata sulla confezione.
– La confezione è aperta o danneggiata.
– Lo strumento è danneggiato.
– Lo strumento presenta palese difetti di sicurezza.

• Non utilizzare un aspiratore a muro (vuoto centralizzato).

• L'estrazione con vuoto può essere eseguita o controllata da solo da medici esperti e addestrati.

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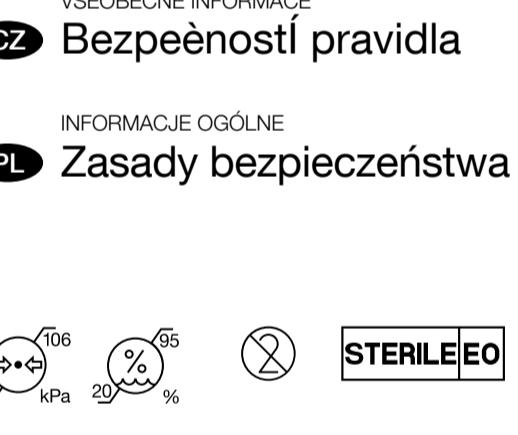
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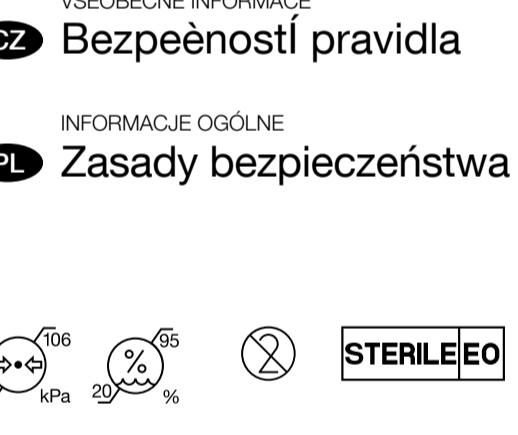
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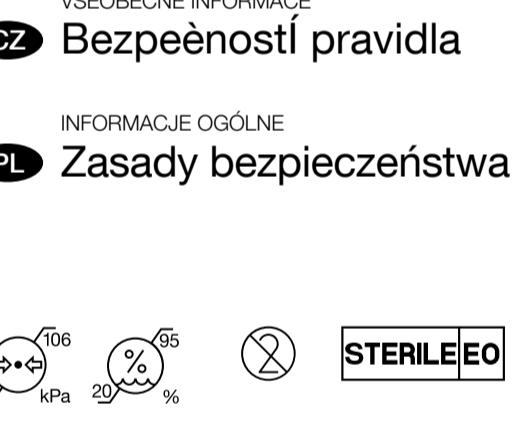
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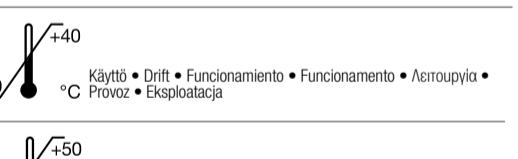
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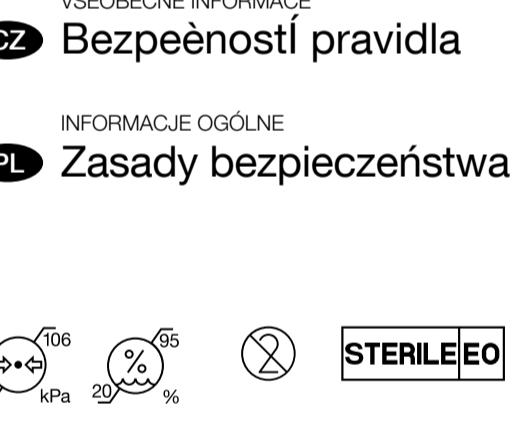
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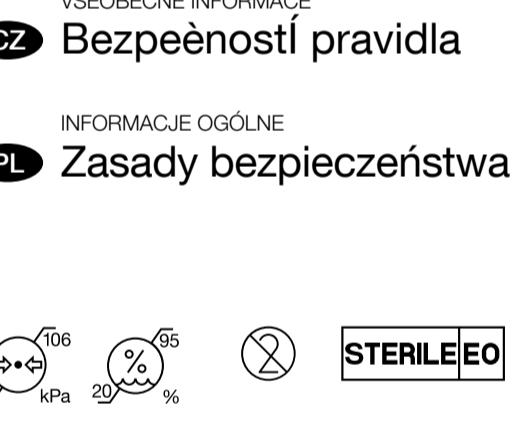
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