

ICE PACK SOFT-GHIACCIO Istantaneo TNT

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Dati normativi

Fabbricante: INTCO MEDICAL (HK) CO., LTD. FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG; operatore certificato da TUV Rheinland secondo la norma EN ISO 13485:2016 Dispositivi medici – Sistemi di gestione per la qualità

Distributore esclusivo: Fisiosviluppi s.r.l.

Classificazione CND: M9001 – DISPOSITIVI CRIOTERAPICI E TERMOTERAPICI

Classe di rischio D.M. : IIa

Numero di Repertorio (RDM): 2420772

Riferimenti e norme: il prodotto è un dispositivo medico marcato CE, secondo il REGOLAMENTO (UE) 2017/745.

Confezionamento: scatola di cartone da 25 buste

Ice pack soft

Ghiaccio istantaneo tnt



Ghiaccio istantaneo monouso, da usare in tutti i casi in cui necessiti la crioterapia e l'uso del freddo. Il materiale della busta assicura un piacevole contatto con le parti sensibili del corpo (es. viso).

UTILIZZO

Il freddo terapeutico riduce il flusso sanguigno nella zona interessata, contribuendo a ridurre l'infiammazione e il gonfiore. Inoltre, il freddo può agire come un analgesico naturale, alleviando il dolore e fornendo un senso di comfort. Indicato per alleviare il dolore e il gonfiore causati da:

- Distorsioni
- Stiramenti
- Contusioni
- Ustioni minori
- Mal di denti
- Punture di insetti

CODICE PRODOTTO	Formato	Peso	Confezionamento	Smaltimento
ST-IP250S	Busta 14x18 cm	250 g	Cartone da 25 buste, pedana da 73 cartoni (1.825 buste)	Residuo secco-indifferenziato (seguire indicazioni Comune di appartenenza)



CARATTERISTICHE

- Contatto soffice con la pelle grazie al materiale in TNT della busta
- Subito pronto all'uso dopo semplice attivazione
- Conformabile ai diversi siti di applicazione

COMPOSIZIONE

Acqua, urea, TNT (testato per il contatto con la pelle)

Busta con istruzioni per l'uso ed etichetta

IT-ATTENZIONE: Non congelare. Non applicare su cute lesa. Non utilizzare su pazienti con problemi sensoriali. Prima dell'uso conservare a temperatura ambiente. Lo stoccaggio a temperature inferiori potrebbe causare congelamento dopo l'attivazione. Conservare in un luogo asciutto.

AVVERTENZE: tenere fuori dalla portata dei bambini. Nocivo se ingerito. In caso di ingestione accidentale, contattare immediatamente il centro antiposione o un medico. Non forare la borsa esterna. Se la sacca si rompe e il liquido viene a contatto con la pelle o gli occhi, sciacquare immediatamente con acqua e chiamare un medico. Non mescolare con materiali combustibili.

CONTENUTO: Urea, acqua

EN-CAUTION: Do not freeze the bag. Do not use on injured skin. Do not use on sensory impaired patients. Prior to use store at room temperature. Storage at lower temperatures could cause frostbite after activation. Store in a dry place.

WARNINGS: keep out of reach of children. Harmful if swallowed. If accidentally

swallowed contact poison control center or physician immediately. Do not puncture outer bag. If bag breaks and fluid contacts skin or eyes flush with water immediately and call physician. Do not mix with combustible materials.

CONTAINS: Urea, water

ES-PRECAUCIÓN: No congelar la bolsa. No utilizar sobre piel lesionada. No utilizar en pacientes con problemas sensoriales. Antes de su uso, conservar a temperatura ambiente. El almacenamiento a temperaturas más bajas podría causar congelación después de la activación. Almacenar en lugar seco.

ADVERTENCIAS: mantener fuera del alcance de los niños. Nocivo por ingestión. En caso de ingestión accidental, contactar inmediatamente con un centro de toxicología o un médico. No perforar la bolsa exterior. Si la bolsa se rompe y el líquido entra en contacto con la piel o los ojos, lavar inmediatamente con agua y llamar al médico. No mezclar con materiales combustibles.

CONTIENE: Urea, agua

FR-ATTENTION: Ne pas congeler le sachet. Ne pas utiliser sur une peau lésée. Ne pas utiliser sur des patients souffrant de troubles sensoriels. Avant utilisation, conserver à température ambiante. Le stockage à des températures inférieures pourrait provoquer des gelures après l'activation. Stocker dans un endroit sec.

AVERTISSEMENTS: garder hors de portée des enfants. Nocif en cas d'ingestion. En cas d'ingestion accidentelle, contacter immédiatement le centre antiposion ou un médecin. Ne pas percer le sac extérieur. Si le sac se brise et que le liquide entre en contact avec la peau ou les yeux, rincer immédiatement à l'eau et appeler un médecin. Ne pas mélanger avec des matériaux combustibles.

CONTIENT: Urea, eau

DE-VORSICHT: Den Beutel nicht einfrieren. Nicht auf verletzter Haut verwenden. Nicht bei sensorisch eingeschränkten Patienten anwenden. Vor der Anwendung bei Raumtemperatur lagern. Die Lagerung bei niedrigeren Temperaturen kann nach der Aktivierung zu Erfrierungen führen. An einem trockenen Ort lagern.

WARNUNG: Außerhalb der Reichweite von Kindern aufbewahren. Gesundheitsgefährlich bei Verschlucken. Bei versehentlichem Verschlucken sofort Giftinformationszentrale oder Arzt verständigen. Außenbeutel nicht durchstechen. Wenn Beutel reißt und Flüssigkeit mit Haut oder Augen in Berührung kommt, sofort mit Wasser spülen und Arzt rufen. Nicht mit brennbaren Materialien mischen.

ENTHÄLT: Harnstoff, Wasser

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Made in PRC

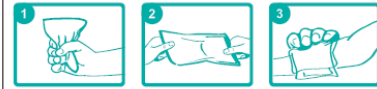
MedNet EC-REP GmbH
Berkstrasse 10,
48163 Münster
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FISIOSVILUPPI SRL
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CE 0197

REF
ST-IP250S



IT
Per alleviare il dolore e il gonfiore causati da distorsioni, stramenti, contusioni, ustioni minori, mal di denti e punture di insetti

ISTRUZIONI

Non forare la borsa interna. Meglio se attivato tra 0-27 °C (32-80 °F)

1. Individuare la sacca interna, premere con forza per rompere la sacca interna del fluido
2. Agitare brevemente per mescolare il contenuto
3. Applicare sulla parte interessata

EN
For relief of pain and swelling caused by sprains, strains, contusions, minor burns, toothaches and insect bites

INSTRUCTIONS

Do not puncture inner bag. Best if activated between 0-27 °C (32-80 °F)

1. Locate inner pouch, squeeze firmly to rupture inner fluid pouch
2. Shake briefly to mix contents
3. Apply to the affected area

ES
Para aliviar el dolor y la hinchazón causados por esguinces, torceduras, contusiones, quemaduras leves, dolores de muelas y picaduras de insectos

INSTRUCCIONES

No perforar la bolsa interior. Mejor si se activa entre 0-27 °C (32-80 °F)

1. Localizar la bolsa interior, apretar firmemente para romper la bolsa interior de fluido
2. Agitar brevemente para mezclar el contenido
3. Aplicar sobre la zona afectada

FR
Pour soulager la douleur et l'enflure causées par les entorses, les foulures, les contusions, les brûlures mineures, les maux de dents et les piqûres d'insectes

INSTRUCTIONS

Ne pas percer le sac intérieur. Mieux si activé entre 0-27 °C (32-80 °F)

1. Localiser la poche intérieure, presser fermement pour rompre la poche intérieure de fluide
2. agiter brièvement pour mélanger le contenu
3. Appliquer sur la zone affectée

DE
Zur Linderung von Schmerzen und Schwellungen bei Verstauchungen, Zerrungen, Prellungen, leichten Verbrennungen, Zahnschmerzen und Insektenstichen

ANLEITUNGEN

Innenbeutel nicht durchstechen. Am besten bei einer Aktivierung zwischen 0-27 °C (32-80 °F)

1. Lokalisieren Sie den inneren Beutel und drücken Sie ihn fest zusammen, um den inneren Flüssigkeitsbeutel zu zerreiß
2. Kurz schütteln, um den Inhalt zu mischen
3. Auf die betroffene Stelle auftragen

LOT



MD



Dichiarazione di Conformità



INTCO MEDICAL(HK) CO., LTD.

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Website: www.intco.com.cn

Document Number : CE-DC-001

Version: A/5

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

INTCO Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART
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Borkstrasse 10, 48163 Muenster,
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We, the manufacturer, herewith declare that the products

Cold Packs

(HypaCool Instant Cold Pack, Instant Ice Pack Mini, Instant Plus Ice Pack, Instant Ice Pack, INSTANT COLD COMPRESS, HOT & COLD COMPRESS, Instant Soothe COLD pack, Cold Pack, Instant Freeze, Instant cold pack, Instant Cold Compress, cold pad, Instant Cool Pack, Instant Perineal Cold Pack, Cool Power Compress, CoolPack Mini, Cool Pack Midi, Cool Pack Maxi, Cold Compress, Ice Pack - Ghiaccio istantaneo , Ghiaccio istantaneo TNT

Model codes

(T129525, Q2281, 7710, 713, 710, ICE1069, 151168, 122864, INSD, N14843, N14844, 09135, 09136, 007909, 100196, 0, 99228, 99242, ICE0609, ICE0506, ICE1125, ICE0505, 751520-Q, 751315-Q, KID2, 122865, 132935, HY-303, 913-001, 30649, 193349.2, 1130109, I114-15*23, I1114-13*15, 04-018M, 25.00200, Q2281PK288 , ST-IP250 , ST-IP250S)

UMDNS Code: 10932

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX, Rule 9 of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex V and Annex VII of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: **DD 2068388-1**
Issue date: 11.09.2020
Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of

1/2



Fisiosviluppi s.r.l. via Monfalcone 12 Ragusa
Documento: Scheda tecnica
Prodotto: Ghiaccio istantaneo TNT
Codice/i: ST-IP250S

Data: 15/05/2023
Revisione: 0
Note rev:

**INTCO MEDICAL(HK) CO., LTD.**

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
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Tel: +86 511 83174088 Fax: +86 511 83174188

Website: www.intco.com.cn

produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **INTCO Medical (HK) Co., Limited**

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG

Zhenjiang
Place, date

Zhenjiang 2022.2.11

Sun quihua Manager
Legally binding signature, Function

Certificato CE

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2068388-1

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG,
P.R. China

Products: Warmers, Cold Packs, Hot Packs
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Disposable Surgical Masks, Disposable Surgical Gowns, Disposable Surgical Caps, Surgical Drapes
Replaces Approval, Registration No.: DD 60144577 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15096008 012

Effective date: 2020-09-11

Expiry date: 2024-05-26

Issue date: 2020-09-11



Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 - 90431 Nürnberg - Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2068388-1

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG,
P.R. China

The scope of certification also includes the following additional facilities:

No.	Location	Product groups manufactured
/01	Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China	Aspects of manufacture concerned with securing and maintaining sterile conditions of Disposable Surgical Masks, Disposable Surgical Gowns, Disposable Surgical Caps, Surgical Drapes
/02	Jiangsu Intco Medical Products Co., Ltd. No. 77 Yandunshan Road, Dagang Zhenjiang 212132 Jiangsu P.R. China	Warmers, Cold Packs, Hot Packs

Report No.: 15096008 012

Effective date: 2020-09-11

Expiry date: 2024-05-26

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