



## ENGLISH

BEFORE USING THE DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

IF YOU ARE USING THE CRYO/CUFF WITH THE AIRCAST CRYO/CUFF IC UNIT BE SURE YOU READ AND UNDERSTAND ALL INSTRUCTIONS LOCATED IN THE AIRCAST CRYO/CUFF IC INSTRUCTIONS FOR USE.

**INTENDED USER PROFILE:** The intended user should be a licensed medical professional, the patient, the patient's caretaker, or a family member providing assistance. User should be able to:

- Read and understand the directions, warnings and cautions.

**OPERATING PRINCIPLE:** The AirCast Cryo/Cuff provides cold therapy and compression. **INTENDED USE/INDICATIONS:** The AirCast Cryo/Cuff combines focal compression with cold to minimize swelling and pain.

**FREQUENCY OF USE:** The length of use and frequency of use of the Cryo/Cuff are determined by the healthcare professional depending on individual patient's needs. This device can be cold enough to cause serious injury be sure to check skin frequently.

**CONTRAINDICATIONS:** Cryotherapy should not be used on persons with Raynaud's or other vasospastic disease, cold hypersensitivity, decreased skin sensitivity, compromised local circulation, diabetes, sickle-cell anemia, arteriosclerosis, cryoglobulinemia, hypercalcemic paralyzing disorders or other peripheral vascular diseases causing ischemia or poor local circulation, local tissue infection, cold allergy, cold hypersensitivity, previous cold injury and polyoma cold haemoglobinuria.

**DO NOT USE** if you are allergic to any of the materials contained within this product.

### WARNINGS AND CAUTIONS:

- This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the Cuff (DO NOT use if you cannot check your skin condition frequently). People are sensitive to cold in diverse ways and may react differently to cold treatment.

- Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, welts, irritation or other changes in skin condition under the Cuff or around the treatment area. If you experience any of these conditions, immediately discontinue use of the device and contact your physician.

- Patient skin condition checks must occur every 1-2 hours on a routine basis. Caution must be taken by routinely monitoring the patient during use in children, elderly, incapacitated patients, severe cardiovascular diseases, and those with decreased skin sensitivity or circulation due to poor nutrition, medications (e.g. beta blocker or premedication, narcotics), tobacco and alcohol use.

- If such monitoring is to occur outside of the licensed healthcare professional, the user must ensure that the patient or patient caretaker understands how such monitoring is to be conducted.

- It is recommended that, at least 20 minutes of cessation should be encouraged between 2 hour long cryotherapy sessions.

- When applying the device wrap to the skin, apply a barrier (e.g. cloth or bandage) between the wrap and your skin, and do not wrap it around the area tightly. No part of the wrap should touch the skin for any period of time.

- Check for moisture. If moisture is present on the Cuff, immediately discontinue use of the device.

- Do not use an elastic wrap in conjunction with the Cryo/Cuff.

- Dressings used under the Cryo/Cuff should be applied lightly.

- When filling the Cryo/Cuff, do not raise the cooler higher than 15 inches (38 cm) above the cuff to avoid excessive pressure.

- Reduce pressure with any sense of discomfort, numbness or tingling of the limb.

- The Cryo/Cuff is designed for single patient use only and may be used on the same patient for the length of treatment.

- The device should be cleaned if it is used on the same patient for an extended period of time (see "Cleaning Instructions" for cleaning information).

- Use small parts and packaging materials away from small children and animals.

- These items pose a risk for suffocation or strangulation.

- It could be unsafe to use accessories, detachable parts and materials, or interconnect to other medical equipment.

- Otherwise modified equipment may be unsafe to use.

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## ESPAÑOL

ANTES DE UTILIZAR ESTE DISPOSITIVO, LEA POR FAVOR ESTAS INSTRUCCIONES COMPLETA Y DETENIDAMENTE. EL USO CORRECTO ES FUNDAMENTAL PARA EL FUNCIONAMIENTO APROPIADO DE ESTE DISPOSITIVO.

SI ESTÁ UTILIZANDO EL CRYO/CUFF CON LA UNIDAD AIRCAST CRYO/CUFF IC, ASEGÚRESE DE LEER Y COMPRENDER TODAS LAS INSTRUCCIONES DEL MANUAL DE USO DEL AIRCAST CRYO/CUFF IC.

**PERFIL DEL USUARIO OBJETIVO:** El usuario al que va dirigido debe ser un profesional médico con licencia, el paciente, la persona que provee a este cuidados primarios o los miembros de la familia que brindan asistencia. El usuario debe ser capaz de realizar lo siguiente:

- Leer y comprender las direcciones, advertencias y precauciones.

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## DEUTSCH

VOR GEBRAUCH DER VORRICHTUNG BITTE DIE GEBRAUCHSANWEISUNG SORGFÄLTIG DURCHLESEN. DIE EINWANDFREIE FUNKTION DER VORRICHTUNG IST NUR BEI RICHTIGEM ANLEGEN GEWÄHRLEISTET.

WENN SIE DIE CRYO/CUFF MASCHETTE MIT DER AIRCAST CRYO/CUFF IC-EINHEIT EINSETZEN, VERWISSEN SICH SICH, DASS SIE ALLE ANWEISUNGEN LESSEN UND BEACHTEN. DIESE SIND DIE GEBRAUCHSANLEITUNG FÜR DAS AIRCAST CRYO/CUFF IC ENTHALTEN SIND.

**ANWENDERPROFIL:** Der Anwender sollte eine zugelassene medizinische Fachkraft, der Patient, der Betreuer des Patienten oder ein betreuendes Familienmitglied sein. Der Anwender sollte in der Lage sein:

- Die in der Gebrauchsanweisung aufgeführten Anweisungen, Warnungen und Vorsichtsmaßnahmen zu lesen, zu verstehen und physisch in der Lage sein, diese auszuführen.

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## ITALIANO

PRIMA DELL'USO, LEGGERE INTEGRAMENTE E ATTENTAMENTE QUESTE ISTRUZIONI. LA CORRETTA APPLICAZIONE È DI FONDAMENTALE IMPORTANZA PER UN BUON FUNZIONAMENTO.

SE SI USA CRYO/CUFF INSIEME ALL'UNITÀ AIRCAST CRYO/CUFF IC, ACCERTARSI DI LEGGERE E COMPRENDERE INTEGRALMENTE LE ISTRUZIONI PER L'USO DI AIRCAST CRYO/CUFF IC.

**PROFILIO UTENTE:** l'utente cui il prodotto è destinato deve essere un medico professionista, il paziente, la persona che si prende cura di un familiare che lo assiste. L'utente deve essere in grado di:

- leggere, comprendere e seguire le istruzioni, le avvertenze e le precauzioni riportate nelle informazioni per l'uso.

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## FRANÇAIS

LIRE ATTENTIVEMENT LA TOTALITÉ DES INSTRUCTIONS SUIVANTES AVANT D'UTILISER LE DISPOSITIF. UNE MISE EN PLACE CORRECTE EST INDISPENSABLE AU BON FONCTIONNEMENT DU DISPOSITIF.

EN CAS D'UTILISER LE DISPOSITIF EN COMBINATIE AVEC L'UNITÉ AIRCAST CRYO/CUFF IC, VÉRIFIER A BIEN LIRE ET COMPRENDRE L'ENSEMBLE DES INSTRUCTIONS POUR L'USO DE L'UNITÉ AIRCAST CRYO/CUFF IC.

**PROFIL DE L'UTILISATEUR A QUI LE DISPOSITIF S'ADRESSE :** Le dispositif s'adresse à un médecin autorisé, le patient, l'aidé-soignant ou un membre de la famille qui prodigue les soins au patient. L'utilisateur doit être capable de :

- Lire, comprendre et être physiquement apte à respecter toutes les consignes, les avertissements et les précautions qui figurent dans le mode d'emploi.

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