English

Product Number H8410**650/651/652**1

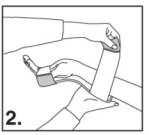
Dale® Bendable ArmBoard

LATEX Latex Free

All-In-One System

Product Description

The Dale Bendable ArmBoard replaces traditional Armboards. The Bendable ArmBoard allows the hand and wrist to maintain their natural position while securely and comfortably preventing catheter movement. The ArmBoard positions and secures the hand and wrist during insertion and monitoring of arterial lines in the operating room, recovery room, and patient care units. The ArmBoard can be custom-shaped to any desired position. It is covered in a soft, comfortable material, and fastened with adjustable VELCRO® straps. It can be used to secure the thumb during extension of the wrist for better access to the radial artery. This leads to more trouble-free A-Line insertions and facilitates invasive monitoring of arterial blood pressure and arterial blood gases for extended periods.



Application Instructions

1. Align wrist with ArmBoard and bend to desired position.
2. Wrap straps around hand and board to desired tension. Press VELCRO® hook fasteners to secure.

For single patient use.

Ordering Information

#H8410**650**1	Dale® Bendable ArmBoard Large. Individually packaged. Sold in boxes of 10. 23 cm x 12 cm (9" x 4 ¾")
#H8410**651**1	Dale® Bendable ArmBoard Medium. Individually packaged. Sold in boxes of 10. 14 cm x 8 cm (5 ½" x 3")
#H8410**652**1	Dale® Bendable ArmBoard Small. Individually packaged. Sold in boxes of 10. 11 cm x 4 cm (4 ½" x 1 ¾")

Dale® medical products are available from your preferred hospital/medical supply dealer.

US Patent Number 5,845,643

MR

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Rev C pk-650/651/652 INT

(Česky, Dansk, Nederlands, English, Suomi, Français, Deutsch, Ελληνικά, *Magyar, Italiano,* 日本語, 한국어, *Norsk, Português, Español, Svenska,* ภาษาไทย, *Türkçe)*

MRI Information

MR Conditional

The **Dale® Bendable ArmBoard, #650 Large** was determined to be MR-conditional.

The findings of the MRI results for the Dale 650 ArmBoard apply to the smaller versions (#651, #652, and #653) of the ArmBoards, made from the same materials.

Non-clinical testing demonstrated that the Dale Bendable ArmBoard, #650 Large is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the Dale Bendable ArmBoard, #650 Large produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +2.6°C

Therefore, the MRI-related heating experiments for the Dale Bendable ArmBoard, #650 Large at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +2.6°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Dale Bendable ArmBoard, #650 Large. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 20-mm relative to the size and shape of the Dale Bendable ArmBoard, #650 Large.

Pulse Sequence	Signal Void Size	Plane Orientation
T1-SE	16,961-mm^2	Parallel
T1-SE	1,773-mm^2	Perpendicular
GRE	20,816-mm^2	Parallel
GRE	2,224-mm^2	Perpendicular

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Rev A
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