



PRODUCT GUIDE & USER MANUAL

XT-4000-01C Nurofit™ Cushion

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GENERAL PRECAUTIONS

⚠ WARNING STATEMENTS

! WARNING ! No modification of this equipment is allowed. If any part of this device experiences a catastrophic load, appears damaged or functions improperly, discontinue use immediately and contact Qfix at +1 484-720-6053 or tech.support@qfix.com.

! WARNING ! Monitor patient to determine whether appropriate stabilization is achieved. Qualified personnel should determine suitability of the device for use for particular patient.

! CAUTION ! Monitor patient condition during use.

! CAUTION ! Do NOT overinflate.

SERIOUS INCIDENTS


Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

MR MRI SAFETY INFORMATION

Non-clinical testing has demonstrated Nurofit Head Cushion to be MR Safe.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.

	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
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INTENDED USE

This device is intended to position the head during imaging procedures including radiographic and interventional radiology procedures. The device is intended to be used in a clinical environment by trained technicians and clinicians.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

Patient Target Groups

Patients undergoing general medical or surgical procedures involving diagnostic imaging.

Intended Users

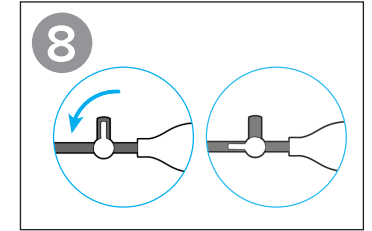
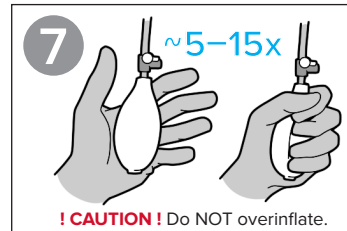
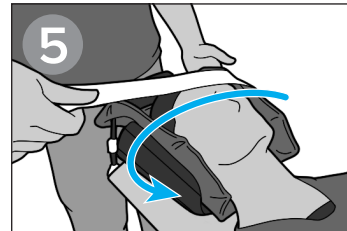
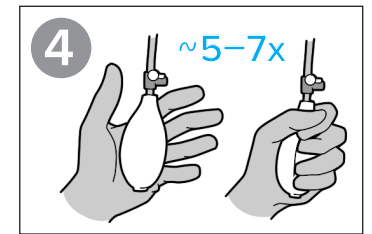
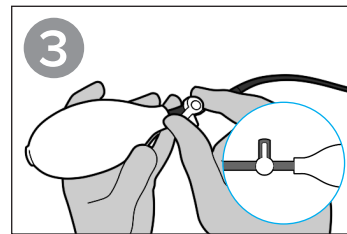
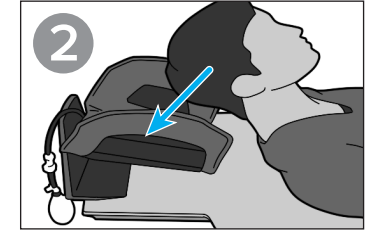
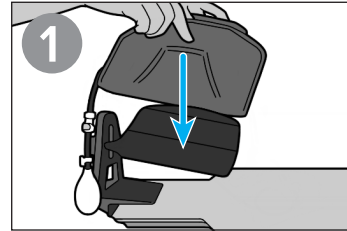
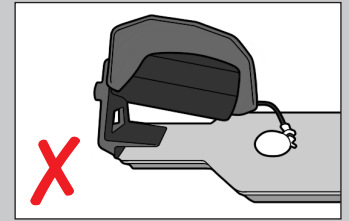
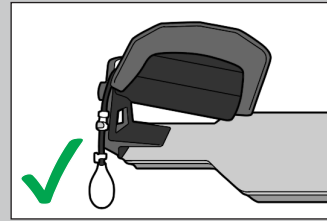
The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

REFERENCES

REF	DEVICE	PRODUCT GUIDE & USER MANUAL
8002505 & XT-4000-01	DSA-3Q Head Holder & Nurofit Head Support	2007156

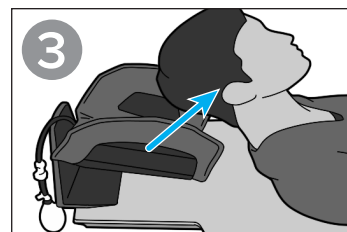
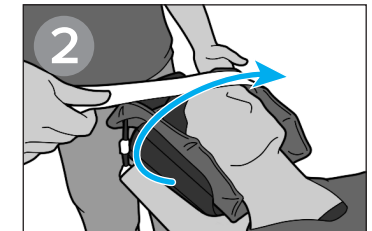
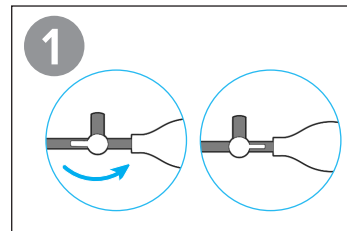
OPERATING INSTRUCTIONS

Proper Orientation



! CAUTION ! Do NOT overinflate.

REMOVAL



Nurofit is a trademark of Qfix.