

MR Safety Information
MR Conditional



only for US-Users

If you have questions, please contact:

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The *proGAV 2.0* valve is MR Conditional.

Non-clinical testing demonstrated that the *proGAV 2.0* valve is MR Conditional.

A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 1,400-Gauss/cm (14.0 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)
- Do not take the *proGAV 2.0 Tools* into the MR environment. They are MR Unsafe.

Under the scan conditions defined above, the *proGAV 2.0* valve is expected to produce a maximum temperature rise of + 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the *proGAV 2.0* valve when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

To confirm that the valves setting has not been altered by exposure to the MRI scanner, the pressure setting of the adjustable unit can be checked with the *proGAV 2.0 Compass*.

Patients should register the conditions under which the implant can be scanned safely with the Medic Alert Foundation (www.medicalert.org) or equivalent organization.

Revision:

Op.-Datum | Op.-Date | Date de l'opération

Grund | Reason | Cause

Ventil | Valve | Valve

Ventilnummer | Valve N° | N° de la Valve

Druckstufe(n) | Pressure range(s) | Niveau(x) de pression

Ventrikelskatheter | Ventricular catheter | Cathéter ventriculaire

Distaler Katheter | Distal catheter | Cathéter distal

Notiz | Note | Note

Reservoir ☐ ja | yes | oui ☐ nein | no | non

Wo? | Where? | Où?

Änderung der Druckstufe | Change of the pressure configuration
Changement du niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Datum | Date | Date Druckstufe | Pressure setting | Niveau de pression

Bei Fragen bitte wenden an | If you have questions, please contact
Si vous avez des questions, contactez

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proGAV 2.0®

Patientenpass
Patient Data Card
Carte d'identification du patient

Name des Patienten | Name of patient | Nom du patient

Geburtsdatum | Date of birth | Date de naissance

Adresse | Address | Adresse

Telefon | Telephone | Téléphone

Bei diesem Patient wurde ein Ventilsystem zur Behandlung des Hydrocephalus implantiert | This patient has a hydrocephalus shunt system implanted | Ce patient porte une système de dérivation pour le traitement de l'hydrocéphalie

Die Ventile sind bis 3 Tesla MR verträglich und verstellbar.
Non-clinical testing demonstrated that the *proGAV 2.0* valve is MR Conditional.

■ **CHRISTOPH MIETHKE GMBH & CO. KG**

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Klinik Hospital Hôpital
Telefon Telephone Téléphone

Telefon | Telephone | Téléphone

Op.-Datum	Op.-Date	Date de l'opération
Aufkleber Sticker Autocollant		
Ventil Valve Valve		

- verstellbare Differenzdruckeinheit | adjustable DP-unit
Unité à pression différentielle réglable

adj. DP-unit:

☐ thorax ☐ retroauricular

☐ other

gravitational unit:

☐ thorax ☐ retroauricular

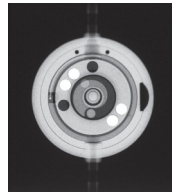
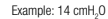
☐ other

Reservoir ☐ ja | yes | oui ☐ nein | no | non

Miethke-Reservoirs sind punktierbar | Punction of Miethke-Reservoirs is possible | Ponction de réservoirs Miethke possible

☐ ja | yes | oui ☐ nein | no | non

Dreieckspitze zeigt den Ventilöffnungsdruck in cmH₂O
 Triangular tip shows opening pressure in cmH₂O
 Pointe triangulaire indique la pression d'ouverture en cmH₂O



Valve compatible avec la résonance magnétique sous conditions, jusqu'à 3 Tesla: la valve ne sera pas involontairement déréglée dans un champ d'IRM de 3 Tesla ou moins, réglage de la pression visible aux rayons X

(SHUNTASSISTANT 2.0)

Druckstufe Opening Pressure Pression d'ouverture	Kodierung Coding Codage
10 cmH ₂ O	
15 cmH ₂ O	
20 cmH ₂ O	
25 cmH ₂ O	
30 cmH ₂ O	
35 cmH ₂ O	