proGAV 2.0 Tool Set®

USA Instructions for Use

CHRISTOPH MIETHKE GMBH & CO. KG

CE/CE 0297

CONTENT

INDICATION	4
DESCRIPTION OF THE INSTRUMENTS	4
proGAV 2.0 Compass	4
proGAV 2.0 Adjustment Tool	4
proGAV Check-mate CE 0297	6
RECOMMENDATION OF PRESSURE LEVELS	7
ADJUSTING THE ADJUSTABLE DP-UNIT	7
CLEANING AND DISINFECTING THE *proGAV Check-mate*	8
RECOMMENDATION FOR STERILISATION	9
RECOMMENDATION FOR STERILISATION OF THE *proGAV Check-mate*	9
CLEANING RECOMMENDATION FOR *proGAV 2.0 Tools* WHICH ARE NOT STERILISABLE	9
MEDICAL PRODUCTS CONSULTANT	10
GENERAL INFORMATION	10

CAUTION
Federal law restricts this device to sale by or on order of a physician!

INDICATION

The *proGAV 2.0* Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the *proGAV 2.0* shunt can be verified by using the *proGAV 2.0 Compass* but must be confirmed by radiograph (x-ray).

The *proGAV 2.0* is a posture dependent hydrocephalus valve. It comprises an adjustable differential pressure unit and a fixed gravitational unit.

Fig. 1: proGAV 2.0 - side view

DESCRIPTION OF THE INSTRUMENTS

Caution: Do not use the *proGAV 2.0 Tools* **nearby pacemakers due to magnets inside the** *proGAV 2.0 Tools***.**

Note: These Tools contain material which has been determined to be MR Unsafe. DO NOT use in or around strong magnetic fields such as MR imaging equipment.

proGAV 2.0 Compass

The *proGAV 2.0 Compass* is used to locate and verify the DP adjustable unit.

If the instrument is opened a template is visible (fig. 2a). Then the valve can be located on the patient's head with the forefinger. Align the template of the *proGAV 2.0 compass* in the direction of cerebral spinal fluid flow and place on the valve.
After the compass is closed (fig. 2b), the pressure setting is indicated automatically.

a) *b)*

Fig. 2: proGAV 2.0 Compass
a) open b) closed

proGAV 2.0 Adjustment Tool

The *proGAV 2.0 Adjustment Tool* is used for adjusting the valve opening pressure of the *proGAV 2.0* from 0 to 20 cmH_2O.

Fig. 3: proGAV 2.0 Adjustment Tool

Each *proGAV 2.0* is calibrated under strict quality control procedures. The presetting of the adjustable DP-unit is 5 cmH_2O, but it must be checked before implantation. The setting is changed in the following steps:

1. Locating the valve
The valve is located under the skin.

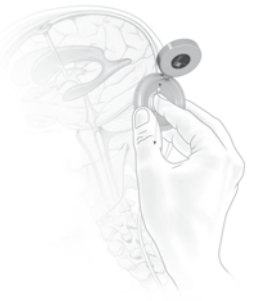


Fig. 4 Locating the valve

The *proGAV 2.0 Compass* must be positioned centrally on the valve. The markings on the instrument "proximal" and "distal" show the flow direction.

2. Verifying the opening pressure
When the compass is closed, the pressure setting is indicated automatically. (fig. 5)

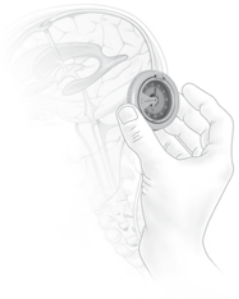
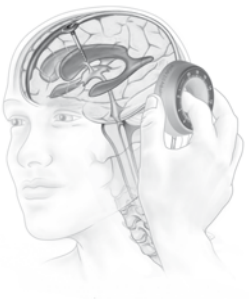


Fig. 5: Verifying the pressure setting

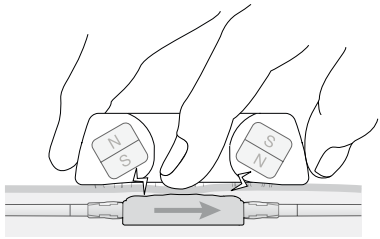
Caution: Placing the *proGAV 2.0 Compass* in a non-central position on the valve can lead to erroneous readings!

The *proGAV 2.0 Compass* is sensitive to external magnetic fields. To exclude undesirable interactions the *proGAV 2.0 Adjustment Tool* should not be in the immediate vicinity of the *proGAV 2.0 Compass* while determining the opening pressure. We recommend a distance of about 30 cm to the *proGAV 2.0 Compass*.

3. Adjusting the opening pressure
The *proGAV 2.0 Adjustment Tool* must positioned centrally on the valve. For a correct placement the valve should be palpated with the forefinger through the opening in the middle of the instrument. The desired pressure setting must point on the scale in direction of the inlet connector and the ventricular catheter. By applying light pressure the rotorbrake will be released and the pressure of the *proGAV 2.0* can be changed.



a)

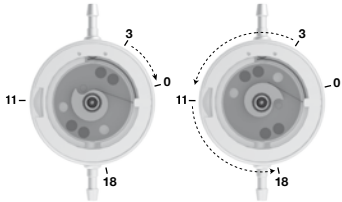


b)

Fig.6: a) and b)
Adjustment with the proGAV 2.0 Adjustment Tool

Caution: The new opening pressure setting of the valve must not differ from the measured opening pressure by more than 8 cmH_2O in any one setting (see chapter 4 "verifying the adjustment").

Example: Opening pressure is to be changed from 3 to 18 cmH_2O. With only one adjustment procedure the rotor would turn in the wrong direction (short way) and would stop at the position 0 cmH_2O. The correct adjustment is in 2 steps: Adjustment from 3 to 11, and from 11 to 18 cmH_2O. The rotor turns correctly.



a) *b)*

Fig. 7: Rotor rotation during adjustment
a) false b) correct

Caution: Ensure that the instrument remains close to the valve during the adjustment procedure.

The *proGAV 2.0* is equipped with a feedback-mechanism. When using the *proGAV 2.0 Adjustment Tool,* pressure on the housing of the valve is created and a resulting acoustic signal (a clicking sound) is produced due to the unique construction of the valve housing. This clicking sound indicates that the rotorbrake is released. Now the rotor can rotate freely. Once the pressure on the valve is released, a clicking sound is heard and the rotor is again locked safely so that the valve is safe against spontaneous re-adjustments.

The clicking sound is well recognizable before implantation. However after implantation, once the valve is filled up, depending on place and texture of the surrounding area of the implant, the acoustic signal could be considerably muted. The clicking sound should generally be audible by the patient itself or via a stethoscope.

When adjusting the *proGAV 2.0* pre-operatively through the packaging, only moderate force with the *proGAV 2.0 Adjustment Tool* should be applied till the valve produces the clicking sound.

From *proGAV 2.0 Adjustment Tool* a magnetic field emanates. Metallic objects and magnetic media strorages should have a sufficient safety margin.

4.Verifying the adjustment

After adjusting the valve by using the *proGAV 2.0 Adjustment Tool*, it must be verified using the *proGAV 2.0 Compass* as described in step 2. If the measured pressure now differs from the intended pressure level, the adjustment procedure has to be repeated from step 3.

Caution: Due to postoperative swelling of the skin the adjustment of the valve setting may be difficult within the first few days.

Caution: If the pressure configuration of the valve cannot be determined with complete certainly by the *proGAV 2.0 Compass,* the use of imaging techniques is recommended.

proGAV Check-mate CE 0297

The *proGAV Check-mate* is delivered sterile and is intended to be re-sterilised. It is possible to change and to verify an applied pressure setting on the valve directly. To verify the actual pressure setting the *proGAV Check-mate* has to be put centrally over the valve. The *proGAV Check-mate* will immediately start to move. If it remains stable, the pressure setting can be read in alignment to the inlet connector.
To adjust a new pressure setting, the *proGAV Check-mate* has to be placed centrally over the valve. The new pressure setting has to point towards the proximal catheter (leading to the ventricle). By pressing down slightly the *proGAV Check-mate*, the brake of the valve is decoupled, the rotor turns and the opening pressure of the *proGAV 2.0* is changed.
Please be aware that the steps for changing the pressure setting should not be more than 8 cmH_2O per step.

Fig. 8: proGAV Check-mate

Caution: Due to magnets inside the *proGAV 2.0 Tools*, do not use the *proGAV 2.0 Tools* nearby pacemakers. Further more do not use the *proGAV 2.0 Tools* nearby MRI scanner, since there is a danger of damaging the MRI-scanner.

RECOMMENDATION OF PRESSURE LEVELS

Adjustable DP-unit	
Standard (children and NPH-patients)	5 cmH_2O
Defensive ((e.g. patients with extremely wide ventricles and highly elevated ICP or aqueductal stenosis)	10 cmH_2O
Special (e.g. patients with pseudotumor cerebri)	15 cmH_2O

Gravitational unit	
Children up to 5 years	20 cmH_2O
Children over 5 years and Adults up to 60 years	25 cmH_2O
Adults over 60 years	20 cmH_2O

The recommendations are based on common patient treatments, but can vary depending on the individual patient´s condition, see also www.miethke.com.

ADJUSTING THE ADJUSTABLE DP-UNIT

Please verify specifically before using any tool for verifying or adjusting the opening pressure:

a) *b)*

Fig. 9 a): proGAV 2.0 Compass
b) proGAV 2.0 Adjustment Tool

For the adjustable DP-unit use either the *proGAV 2.0 Tools* or the first generation *proGAV Tools.*
The first generation *proGAV Tool* Instructions for Use can be obtained by visiting our website at www.aesculapusa.com and clicking the „Products“ menu. If you wish to obtain a paper copy of the Instructions for Use, you may request one by contacting your local Aesculap representative or Aesculap‘s customer service at 1-800-282-9000.
For a combination of *proGAV 2.0* with an **adjustable gravitational-unit, use only** *proSA Tools:*

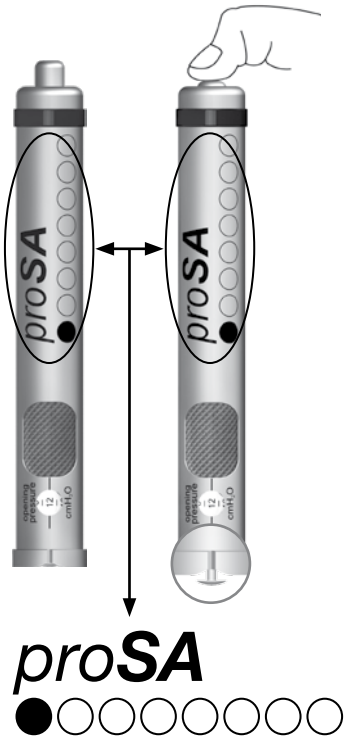


Fig. 10: proSA Adjustment Tool

CLEANING AND DISINFECTING THE
proGAV Check-mate

Avoid damage to the product due to inappropriate cleaning/disinfecting agents and/or exessive temperatures!
- Use cleaning and disinfecting agents approved for surgical steels according to the manufacturer's instructions.
- Observe specifications regarding concentration, temperature and exposure time.

- Do not exceed the maximum allowable cleaning temperature of 55°C.
- Carry out ultrasound cleaning:
  - as an effective mechanical supplement tomanual cleaning/disinfecting.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfecting.
  - as an integrated mechanical support measure for mechanical cleaning/disinfecting.
  - for additional cleaning for products with residues left after mechanical cleaning/ disinfecting.
- Clean and disinfect instruments mechanically, provided they can be securely fixed in machines or storage devices in such a way that they will be thoroughly cleaned.

Manual cleaning/disinfecting
- Check visible surfaces for residues after manual cleaning/disinfecting.
- Repeat the cleaning process if neccessary.

Mechanical cleaning/disinfecting
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).

Mechanical cleaning/disinfecting with manual pre-cleaning

Manual pre-cleaning with ultrasound

Phase	**I**	**II**
Step	Desinfecting ultrasound cleaning	Intermediate rinse
T (°C/°F)	RT (kalt)	RT (kalt)
t (min)	15	1
Conc. (%)	2	-
Water quality	T-W	T-W
Chemie	BBraun Stabimed; aldehydphenol- und QAV-frei; pH = 9	

D-W: Drinking water, RT: Room temperature

Mechanical alkaline cleaning and thermal disinfecting
- Machine type: Single-chamber cleaning/ disinfecting machine without ultrasound
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots)

Stage I
- Clean the product in an ultrasound cleaning bath (frequency 35 kHz). Make certain that all accessible surfaces are moistened.

Stage II
- Rinse the product completely (all accessible surfaces) under running water.

Stage	I	II	III	IV	V	VI
Step	Prerinse	Cleaning	Neutralization	Intermediate rinse	Thermal disinfecting	Drying
T (°C/°F)	<25/ 77	55/ 131	20/ 68	70/ 158	94/ 201	90/ 194
t (min)	3	10	2	1	10	40
Water-quality	D-W	FD-W	FD-W	FD-W	FD-W	-
Chemical	-	-Concentrate, alkaline: pH = 10.9 <5% anionic tensides -1% solution: pH = 10.5	- Concentrate, acid: pH = 2,6 Basis: Citric acid - 1% solution: pH = 3,0	-	-	-

D-W: Drinking water, FD-W: Fully desalinated water (demineralized)

Control, care and inspection

- Allow the product to cool down to room temperature.
- Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Set aside the product if it is damaged.

We recommend putting the *proGAV Check-mate* in a double sterile bag after cleaning. So the next use in the theatre (sterile area) will be prepared as its best.

RECOMMENDATION FOR STERILISATION

Except for the *proGAV Check-mate*, *proGAV 2.0 Tools* can not be sterilised.

RECOMMENDATION FOR STERILISATION OF THE *proGAV Check-mate.*

The *proGAV Check-mate* should be sterilised by steam sterlization (fractionated vacuum process) at 134°C and 5 minutes cycle time.
Notice: For use in the US, please check for further information *www. aesculapusa.com* concerning sterilsation of the *proGAV Check-mate*

CLEANING RECOMMENDATION FOR *proGAV 2.0 Tools* **WHICH ARE NOT STERILISABLE**

Caution: *proGAV 2.0 Tools* **are made from thermal unstable components which are affectable by heat or humidity or chemical agressive substances.**
Do not steep *proGAV 2.0 Tools* **in liquids and keep the inside of the instruments dry!**

Remove surface pollution of the *proGAV 2.0 Tools* after the use immediately with alcohol based cleaners (more than 75% alc.) by a wiping procedure.

The time of impact should be more than 60 sec. and should be depending on the level of pollution. For final cleaning use a dry wipe.

The following cleaning methods are not allowed for the cleaning of the *proGAV 2.0 Tools* (except *proGAV Check-mate*):
Irradiation, Ultrasonic, Sterilization, Machine preparation, Inserting into liquids.

MEDICAL PRODUCTS CONSULTANT

In compliance with the requirements of the European law MDD 93/42/EEC, Christoph Miethke GmbH & Co. KG names medical product consultants as the individuals to be addressed with all queries concerning the products:

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GENERAL INFORMATION

Manufacturer	**Christoph Miethke GmbH & Co. KG**
Product name	*proGAV 2.0 Tool Set*
Intended use	Treatment of Hydrocephalus
Store in a clean, dry place	

CE 0297

CE marking according to directive 93/42/EEC
Technical alterations reserved

Manufacturer acc. MDD 93/42/EEC:

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