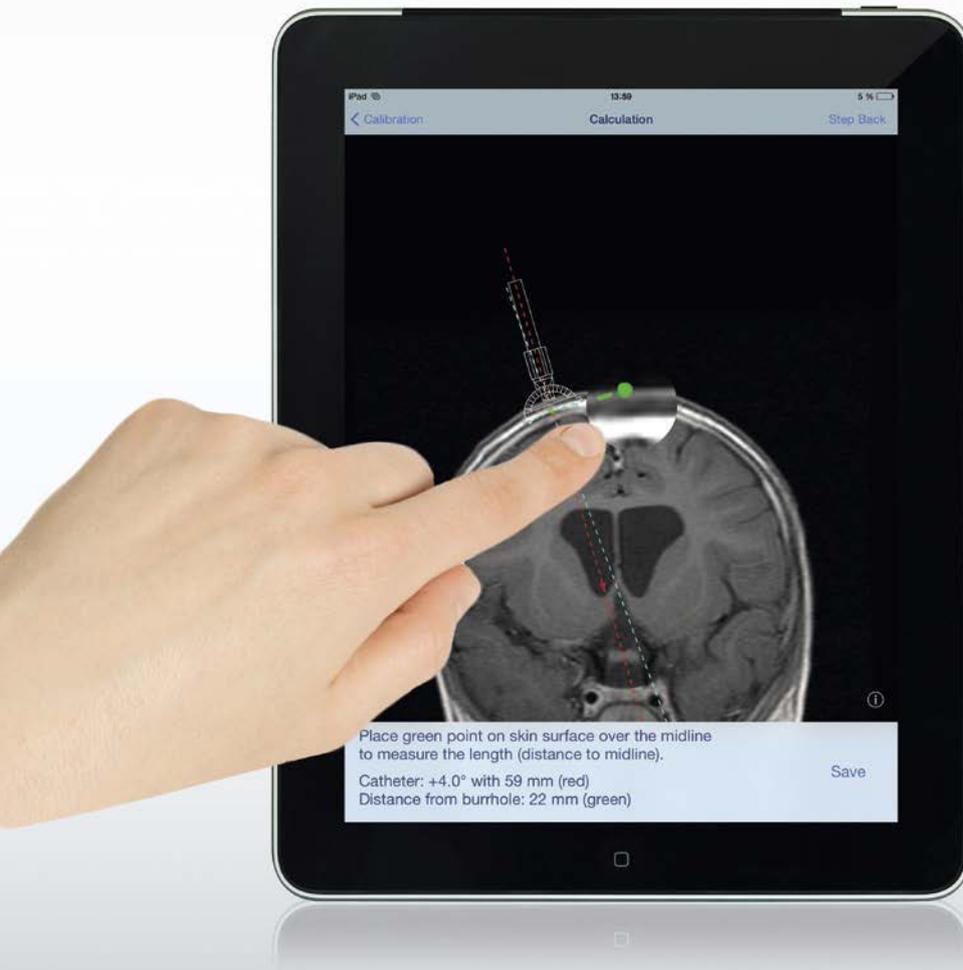


WE UNDERSTAND.



NEUROSURGERY

THOMALE GUIDE

NAVIGATION INSTRUMENT & SOFTWARE

For the controlled neurosurgical placement of a ventricular catheter

THOMALE GUIDE

THE INSTRUMENT

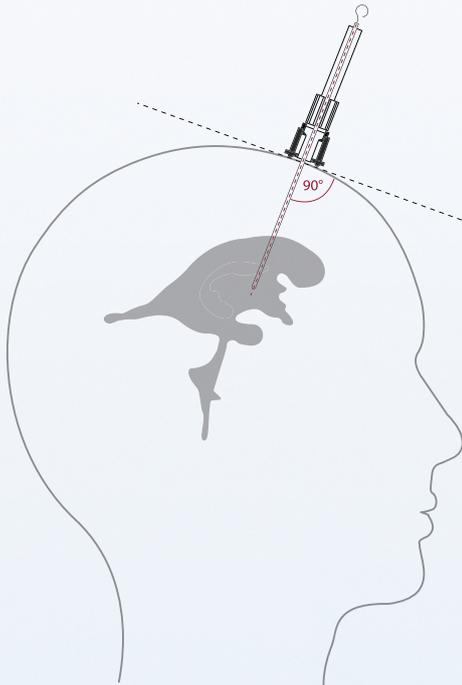


Fig. 1: THOMALE GUIDE in the sagittal plane

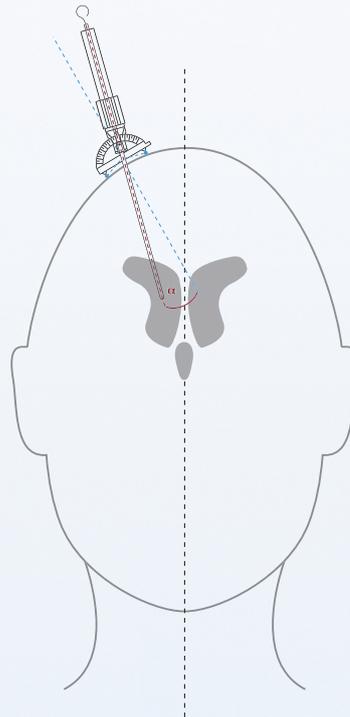


Fig. 2: THOMALE GUIDE in the coronal plane (pointed skull shape)

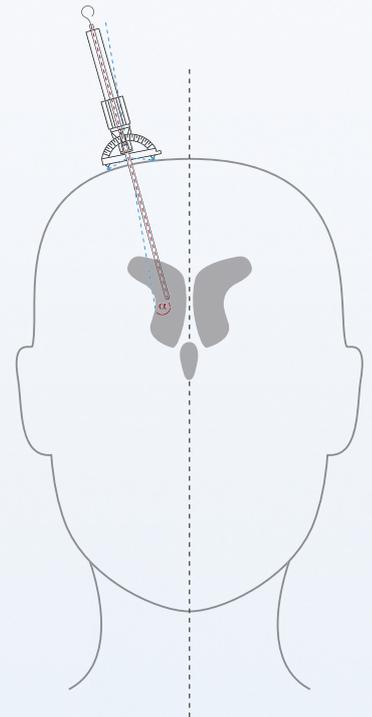


Fig. 3: THOMALE GUIDE in the coronal plane (flat skull shape)

Different studies show that a freehanded ventricular catheter placement may lead to multiple attempts of puncture and represents a relevant risk for malpositioning¹. Together with Dr. Thomale (Charité, Berlin) we developed a neurosurgical instrument to precisely place ventricular catheters via a frontal pre-coronal burrhole with only limited efforts of time.

THOMALE GUIDE is a neurosurgical instrument designed for the precise insertion of a ventricular catheter via a frontal pre-coronal burrhole. Used in conjunction with the *THOMALE GUIDE* app for iPhone and iPad, it is a precise, intuitive navigation and insertion aid. The clinical evidence is shown in the multicenter GAVCA study.²

In the sagittal plane, a right angle to the surface (tangent plane) always reaches the ventricles correctly (Fig. 1), whereas in the coronal plane, the angle has to be adjusted to the individual's skull shape in order to allow correct placement of the ventricular catheter (Fig. 2 and 3).

The *THOMALE GUIDE* app permits swift calculation of the coronal insertion angle based on an imported coronal cross-sectional image.

The *THOMALE GUIDE* is used to set this angle, thereby increasing the precision of the ventricular catheter placement.

¹ Huyette et al., 2008 / Saladino et al., 2009 / Hayhurst et al., 2010 / Wilson et al., 2013

² <https://clinicaltrials.gov/ct2/show/NCT01811589>

Please refer to this study by its ClinicalTrials.gov identifier: NCT01811589

THE APP

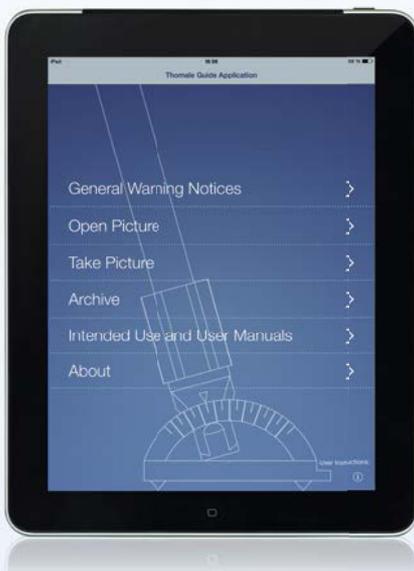


Fig. 4: THOMALE GUIDE app: Selection menu

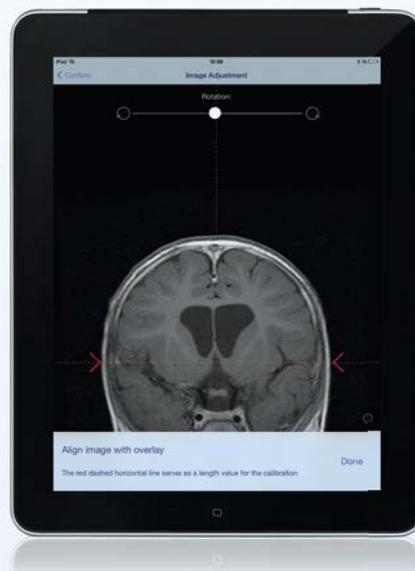


Fig. 5: THOMALE GUIDE app: Fitting the cross-sectional view into a template

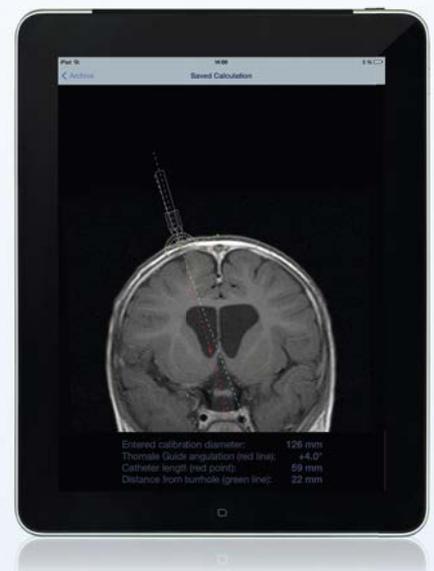


Fig. 6: THOMALE GUIDE app: Displayed results: insertion angle and ventricular catheter length

The *THOMALE GUIDE* app is an accessory for the *THOMALE GUIDE* that is used to determine the following three measures for pre-coronal ventricular puncture:

1. The insertion angle.
2. The length of the ventricular catheter.
3. The position of the burrhole in terms of its distance to the midline.

The app uses the imported coronal cMRI cross-sectional image from directly in front of the patient's third ventricle to permit an individual measurement of the coronal insertion angle in just a few steps. For a cCT image, a coronal reconstruction is required

from a thin-slice data set. The app prompts the user in a few steps to define the position of the burrhole, mark the correct location for guide placement and position the target point for the ventricular catheter tip.

The *THOMALE GUIDE* app then uses this information to calculate the insertion angle to be set for the *THOMALE GUIDE* instrument. The integrated measurement function also permits measurement of the ventricular catheter length and the distance between the burrhole and the anatomical midline. The calculated data is stored in an app archive that can be referred back to when planning the surgical procedure.

» NOW AVAILABLE



THOMALE GUIDE app for iPhone and iPad (Apple App Store).



Free iBook quick start guide (Apple iBooks Store).



The *THOMALE GUIDE* is a reusable, resterilizable instrument. It is supplied in a sterile condition with a catheter guide for Miethke ventricular catheters (2.6 mm internal diameter) plus two additional catheter guides with internal diameters of 3.1 mm and 3.6 mm.

After each use, the *THOMALE GUIDE* must be dismantled into its component parts, cleaned, and sterilized.

The four component parts are quick and easy to reassemble.

ORDERING INFORMATION

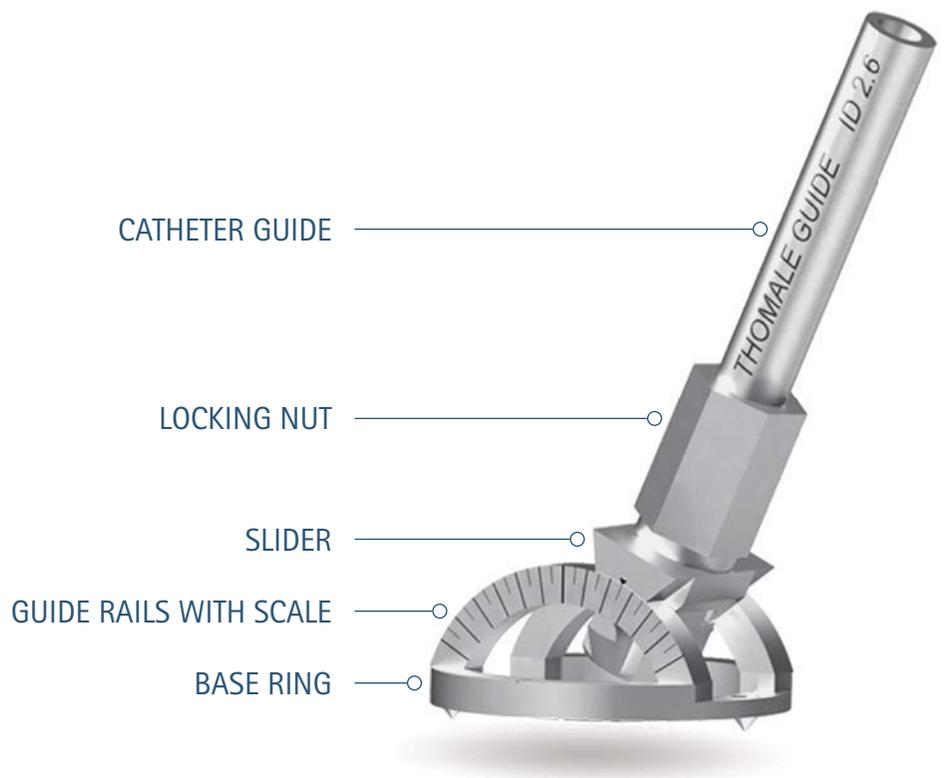
THOMALE GUIDE APP

... for your iPhone or iPad.
Please scan the QR-Code below
for download:



FREE iBook QUICK START GUIDE

... for your iPad.
Please scan the QR-Code below
for download:



Art. no.		Product
FV095R		<p>THOMALE GUIDE, resterilizable, titanium, navigation tool for placing ventricular catheters. It comes with three tube shafts with inner diameters of 2.6, 3.1 and 3.6 mm</p> <p>The THOMALE GUIDE app is an approved medical device and is available free of charge from the Apple App Store.</p>
JF146R		<p>Tray for storage and sterilization of the THOMALE GUIDE</p> <p>External dimensions 85 x 44 x 25 mm, 4 mm perforation</p>

Manufacturer acc. MDD 93/42/EEC

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