FEHLING CONCEPT CEREBELLAR retractor		
Retractor body	NDN-4	CONCEPT CEREBELLAR retractor, body only, 195 mm

Components

NDO-1.....Flexible arm for CONCEPT CEREBELLAR retractor, 7 segments without spatula adapter
NDN-6.....Flexible arm for CONCEPT CEREBELLAR retractor, 8 segments without spatula adapter
NDN-9.....Flexible arm for CONCEPT CEREBELLAR retractor, 11 segments without spatula adapter
NDO-0.....Flexible arm for CONCEPT CEREBELLAR retractor, 15 segments without spatula adapter
NDO-2.....Flexible arm for CONCEPT CEREBELLAR retractor, 21 segments without spatula adapter
NDN-5.....Spatula adapter for flexible arms for CONCEPT CEREBELLAR retractor

Corresponding spatulas are available in a wide variety of designs and must be selected separately by the user based on surgical requirements.

This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.

The CONCEPT CEREBELLAR retractor may only be used, reprocessed and disposed of by qualified medical personnel!

The CONCEPT CEREBELLAR retractor is intended for re-use.

1) Intended purpose

Retractors and retractor components, which are used invasively and for short periods in surgery, serve to separate or hold back various tissue structures, such as skin, bone, muscles and organs.

Additional information regarding the intended purpose

Duration of application: The CONCEPT CEREBELLAR retractor is only intended for short-term use.

Field of application: retractors and retractor components are used for all patients where tissue has to be retracted for a short period of time (max. 24 hours) to improve visibility of the underlying tissue for the surgeon.

User profile: retractors and retractor components may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: retractors and retractor components are only to be used in controlled environments (e.g. OR).

2) Indications

Surgical procedures that require the temporary spreading and holding of various tissue structures, such as skin, bones, muscles and organs, to reach the body structure requiring treatment. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the retractors or retractor blades used are of the correct size and have adequate stability.

3) Contraindication
All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no generally applicable contraindications for the use of retractors. Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient. These include, for example, an increased risk of bone fracture in osteoporosis.

4) Possible adverse effects	
In medical literature, the following adverse effects are described that can possibly occur during the intended use of retractors: - Infections - Impaired wound healing - Lesions of structures (tissues, nerves, vessels) - Necroses - Ischemia of other organs due to compression of blood vessels	
⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
FEHLING INSTRUMENTS CONCEPT CEREBELLAR retractors are non-sterile when delivered and must be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	CONCEPT CEREBELLAR retractors must be handled with care during storage, transportation and cleaning! Avoid striking the CONCEPT CEREBELLAR retractor or applying pressure to its parts so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.

⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time.
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization should be used to activate the shape memory. The following should be observed here: • SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e.g., other instruments or restricted space). • After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of approx. 40°C.
Limitations on reprocessing	Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.

Pretreatment at the place of use	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of pretreatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40°C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40°C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2% Neodisher® MediClean forte with water (potable water quality, <40°C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • During the exposure time, use appropriate brush (not a wire brush) to remove coarse contamination. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.

Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer-disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40°C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® MediClean forte in water (potable water quality) at 55°C • Emptying • Rinse for 2 minutes with water (potable water quality, <40°C) • Emptying • Rinse for 1 minute with cold deionized water (<30°C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90°C) • Dry for 30 minutes (90°C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: Manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert)

	Procedure/Parameters: • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40°C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun (or similar). Ultrasonic cleaning: • Clean for 10 minutes at <40°C with 0.5 - 2% cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments with a water spray gun (or similar) for at least 20 seconds. • Rinse the instruments for at least 10 seconds with water (potable water quality, <40°C). • Deionized water (<40°C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • After cleaning, place the products in an ultrasonic bath (35 kHz, <40°C) with a suitable disinfectant solution (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40°C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120°C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly

Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied prior to sterilization. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging	Individually: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134°C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

Storage	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This requires validation and/or validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.

Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability!

Subject to change without notice.

7) Configuration and application

The CONCEPT CEREBELLAR retractor is based on a retractor which opens and closes according to the scissors principle, as is commonly known in a number of different variants. Its jaws are angled approximately 30° inward from the situs in the distal region and each feature 4 teeth for retracting - mainly - soft tissue. With its curved toothed rail, the retraction width can be locked variably up to a maximum of approx. 110 mm.

In contrast to the standard shape of the previously mentioned scissors-type retractors, the CONCEPT CEREBELLAR retractor has a laterally outwards projecting arm in the middle with a round toothed disc at the outer end which acts as a holder for one flexible arm.

A multi-segment flexible arm can be connected to each of the two aforementioned toothed discs at any angle by means of an adapter which is toothed on both sides. The two toothed discs, which then lie on top of each other, are fixed by a screw with a hinged wing, which passes through both the flexible arm adapter as well as the toothed disc of the basic retractor. The tension of the flexible arm is generated via an internal steel cable, which is shortened and thus stabilized by a threaded mechanism until the shape/curvature desired by the user is achieved. The tensioning process is facilitated by a flexible lever mounted on the proximal end of the flexible arm.

An end link is located at the distal end of the flexible arm which can be rotated 360° around the axis of the flexible arm. At its outermost end, it features a surface angled at approx. 30°, through which a screw with knurled nut passes at right angles. The screw and knurled nut are used to hold a retaining element for flat or stemmed spatulas.

The spatulas held by this aforementioned retaining element are made of shape memory material with a dark ceramic surface. This material allows the purpose-dependent deformation of the spatula and, during the course of reprocessing, enables the spatula to return to its original straight shape.

Figure 1 depicts a configuration example for the CONCEPT CEREBELLAR retractor (1) with the flexible arms (2) and the spatulas (4). Table 1 lists the corresponding components.

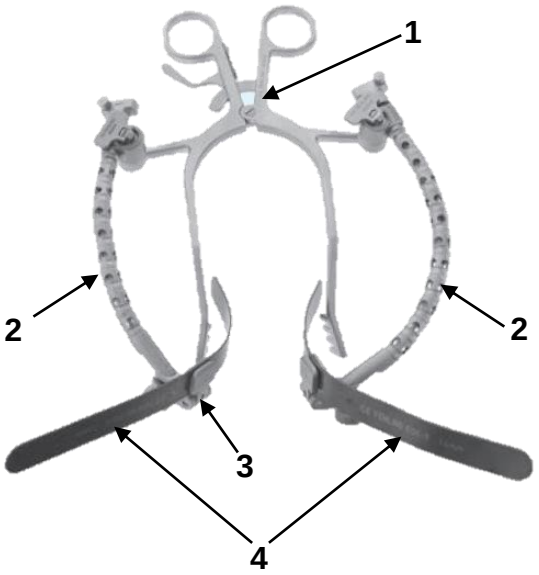

Figure 1: Configuration example for the CONCEPT CEREBELLAR retractor with the flexible arms, spatula adapters and the spatulas

Table 1: List of the corresponding components

	Article no.	Description
1	NDN-4	CONCEPT CEREBELLAR retractor, frame only, 195 mm
2	NDO-1	Flexible arm for CONCEPT CEREBELLAR retractor, 7 segments without spatula adapter
	NDN-6	Flexible arm for CONCEPT CEREBELLAR retractor, 8 segments without spatula adapter
	NDN-9	Flexible arm for CONCEPT CEREBELLAR retractor, 11 segments without spatula adapter
	NDO-0	Flexible arm for CONCEPT CEREBELLAR retractor, 15 segments without spatula adapter
	NDO-2	Flexible arm for CONCEPT CEREBELLAR retractor, 21 segments without spatula adapter
3	NDN-5	Spatula adapter for flexible arms for CONCEPT CEREBELLAR retractor
4	select separately	Spatulas with different designs

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the retractors and retractor components, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Before using retractors and retractor components, ensure that their functionality is not impaired and that there is no damage!
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of retractors and retractor components depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the retractors and retractor components used are of the correct size and have adequate stability.

During use	
⚠	When inserting the retractor blades, ensure that no tissue structures are unintentionally damaged (especially nerves and blood vessels)!
⚠	Too long and too high pressure on the tissue can cause necroses, ruptures, fractures and other lesions!
⚠	Excessive load can cause plastic deformation or breakage of the retractors and retractor components!

Figure 2 depicts the CONCEPT CEREBELLAR retractor with flexible arms mounted on both sides being used on a dummy head.
Here, the tissue surrounding the skull is retracted with the NDN-4 retractor frame (a) to provide optimal access.
The two flexible arms (b) with the respective mounted spatula adapters (c) and spatulas (d) allow the tissue located inside the skull to be retracted following a performed craniotomy.

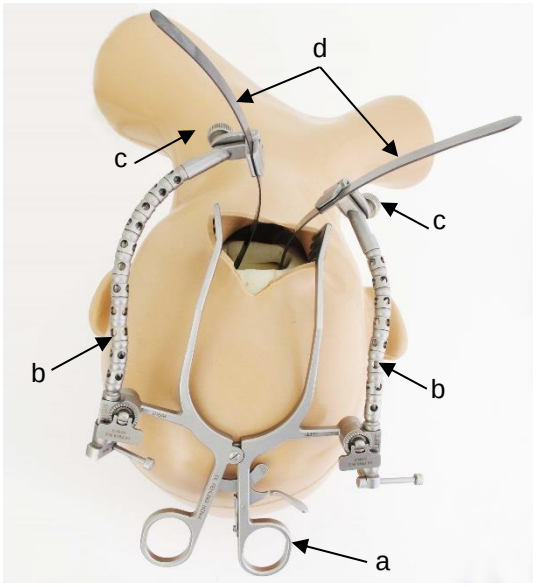

Fig. 2

Figure 3 depicts the close-up of the fully assembled and inserted retractor system.

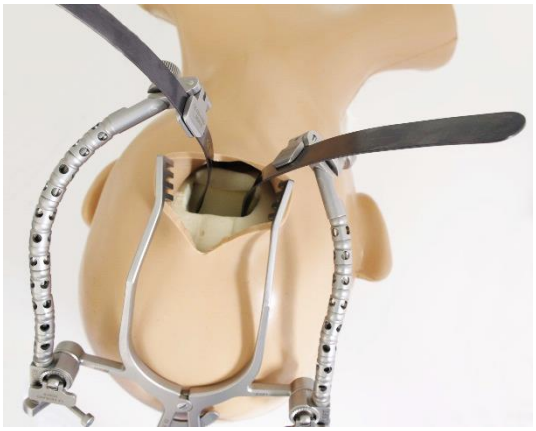
Fig. 3

⚠	Prior to removing retractors and retractor components from the surgical field, ensure that the retractor arms are slowly pushed together again.

8) Required accessories

No accessories are required for using the CONCEPT CEREBELLAR retractor.

9) Assembly

For assembly of the CONCEPT CEREBELLAR retractor please observe the following assembly instructions.

Figure 4 depicts the CONCEPT CEREBELLAR retractor NDN-4 (a) with the flexible arm NDN-6 (b) mounted on the left side with the spatula adapter NDN-5 (c) and the spatula EOI-2 (d).

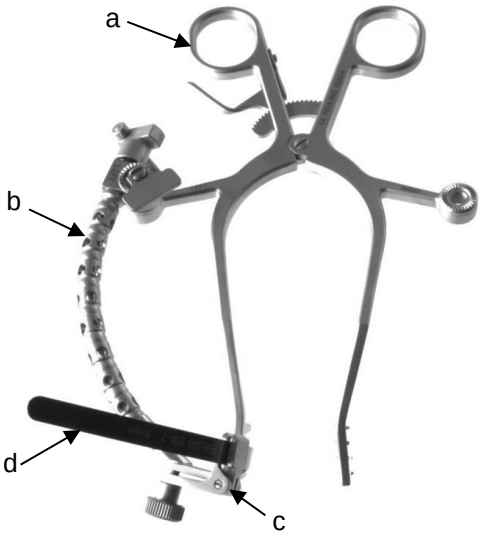

Fig. 4

Figure 5 depicts the CONCEPT CEREBELLAR retractor NDN-4 (a) with the flexible arm NDN-9 (e) mounted on the right side with the spatula adapter NDN-5 (c) and the spatula EOI-8 (e).

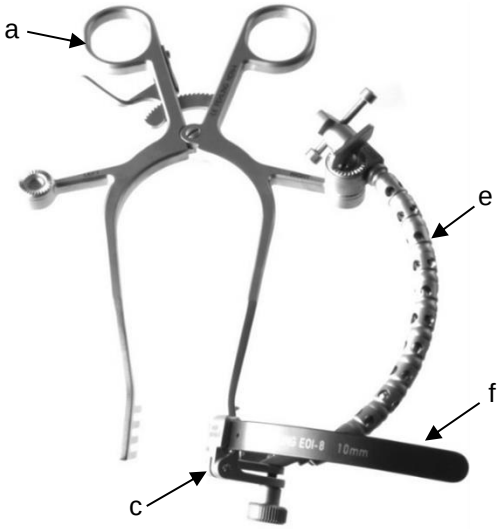

Fig. 5

Figure 6 depicts the CONCEPT CEREBELLAR retractor NDN-4 (a) with flexible arms (b and e) with the spatula adapters (c) and spatulas (d and f) mounted on both sides.

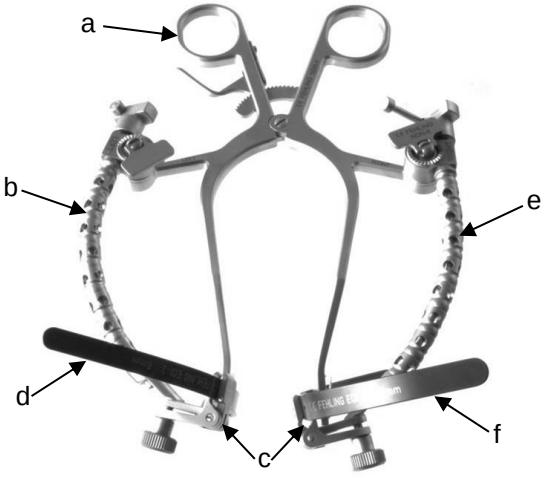

Fig. 6

Assembly of the spatula adapter to the flexible arm

Before the flexible arm can be attached to the CONCEPT CEREBELLAR retractor, NDN-5 spatula adapter must first be assembly on the distal end of the flexible arm. Please observe the following assembly instructions:

Figure 7 shows an example of a felxible arm without a spatula adapter.

Fig. 7: Felxible arm without spatula adapter (exemplary)

To assemble the spatula adapter first turn the knurled nut (g) anti-clockwise until it is completely detached from the threaded rod of the flexible arm (h) (Fig. 8). Hold the flexible arm (h) in place while doing this.

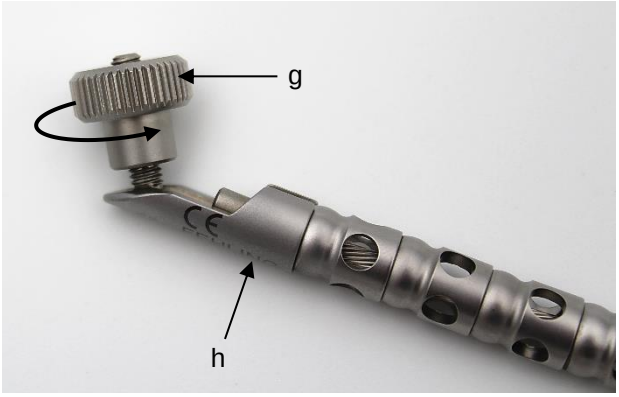

Fig. 8

Figure 9 shows the flexible arm disassembled into its individual parts (flexible arm (h) with knurled nut (g)) and the spatula adapter (c). The spatula adapter (c) is screwed tight between the flexible arm (h) and the knurled nut (g).

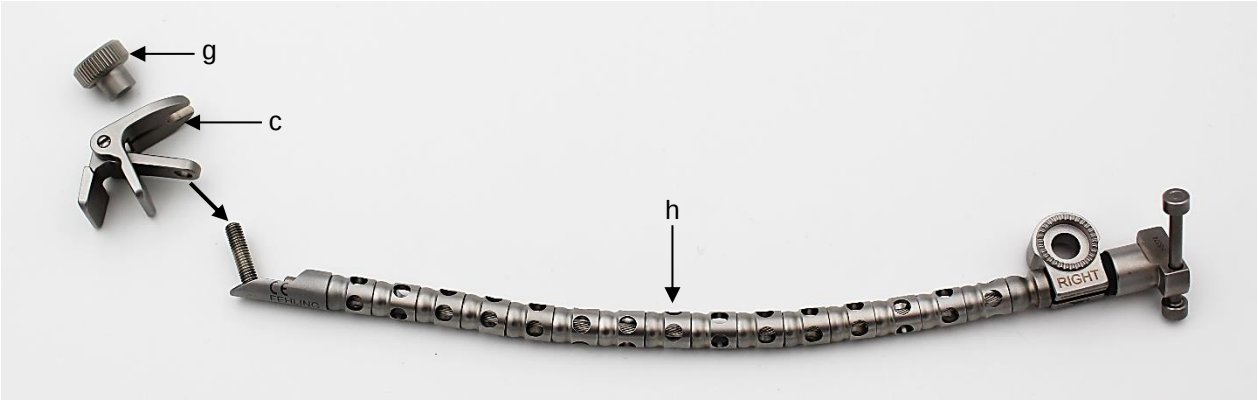

Fig. 9

After removing the knurled nut (g), place the spatula adapter (c) in the threaded rod (i) of the flexible arm (h) as shown in Figure 10a.
Then compress the spatula adapter (c) (Fig. 10b).
When compressed, place the knurled nut (g) on the threaded rod (i) as shown in Figure 10c and tighten clockwise.

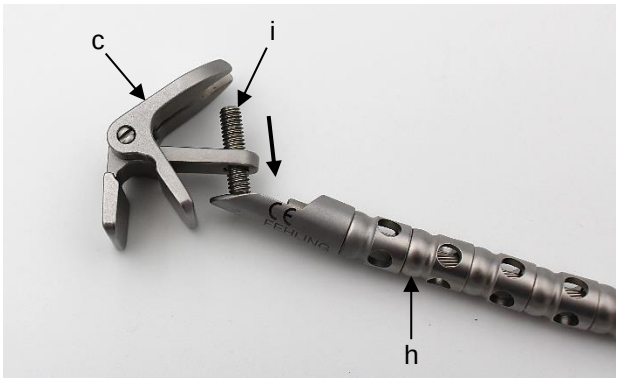

Fig. 10a

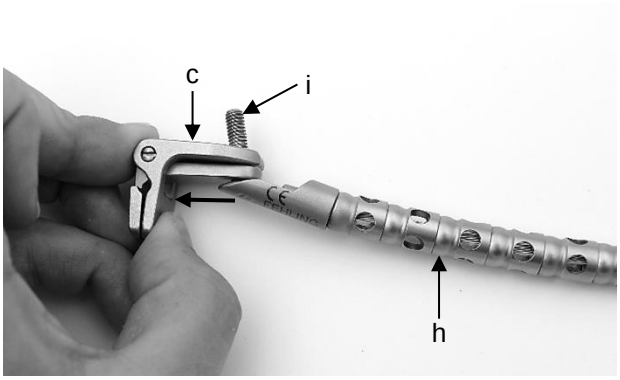

Fig. 10b

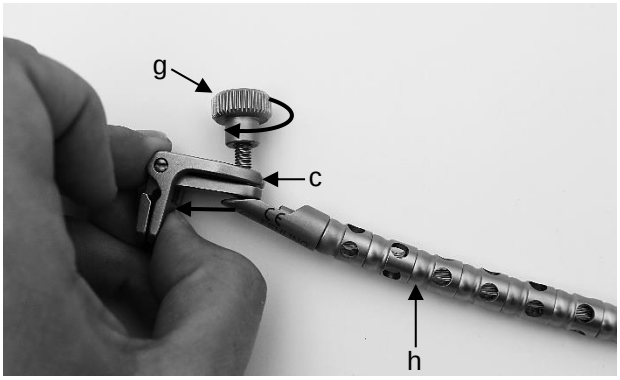

Fig. 10c

Figure 11 shows the flexible arm with attached spatula adapter NDN-5.
After a function test the assembled instrument is now ready for use again and can be attached onto the CONCEPT CEREBELLAR retractor.

Fig. 11

Assembly of the flexible arms to the CONCEPT CEREBELLAR retractor

Figure 12 depicts the attachment of the flexible arm (e) to the CONCEPT CEREBELLAR retractor (a).

The flexible arms can generally be mounted both on the left or right side. This option is possible as there is a toothed profile on both the bottom and the top of the adapter, which engages with the opposite toothed profile on the top of the retractor.

⚠ When changing sides, pull the tilting wing screw (k) completely from the adapter of the flexible arm (e), then turn the flexible arm (e) by 180° and reinsert the tilting wing screw (k). The correct position can be recognized in that the flexible arm (e) is always on the outside of the adapter. There is also a corresponding marking on the flexible arm (e) and CONCEPT CEREBELLAR retractor (a) (see Fig. 14, page 15).

The distal end link of the flexible arm is connected to the spatula adapter at an angle of 30° to the longitudinal axis of the end link, either fixed or detachable. This end link can be rotated 360° when the flexible arm is in a released state. In conjunction with the variable-angle connection of the flexible arm adapter to the retractor frame, these two design features allow optimum alignment of the spatulas with little flexing of the flexible arm.

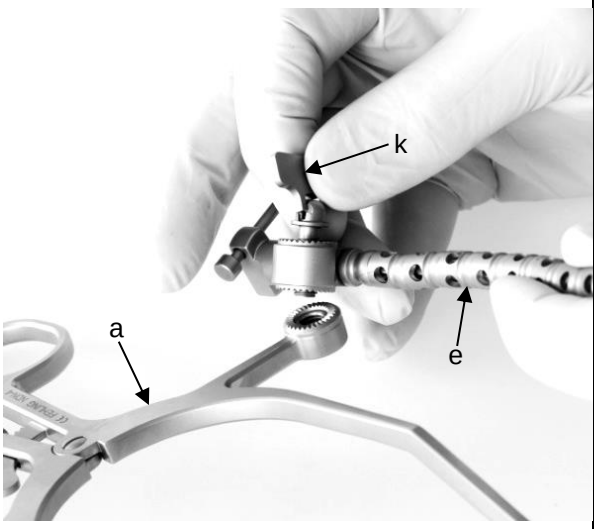

Fig. 12

⚠ Figure 13 depicts the maximum possible position of the flexible arm to the retractor frame at which the flexible arm can still be fixed without any difficulties (approx. 75°). However, angulation as depicted in Figure 13 at, for example, approx. 90° would hinder actuation of the tensioning mechanism of the flexible arm. (This phenomenon is only relevant for long flexible arms where a large radius can be set, e.g. NDO-2)

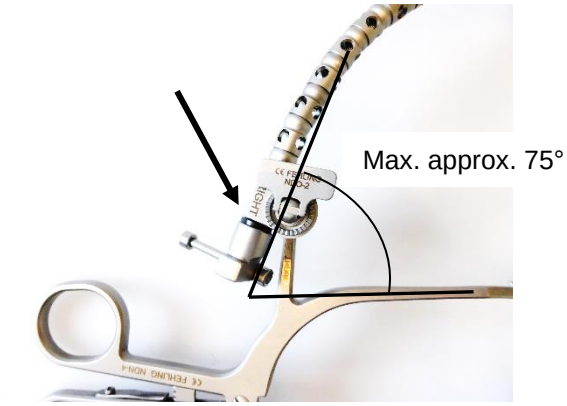

Fig. 13

⚠ Please ensure that the flexible arm is facing in the right direction!

The markings on the flexible arm and on the CONCEPT CEREBELLAR retractor must be the same (Fig. 14).

Marking:
RIGHT – RIGHT
LEFT – LEFT

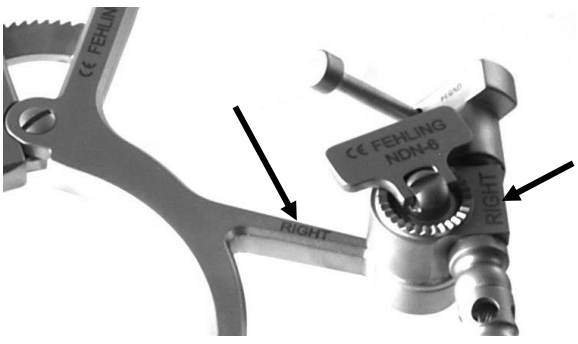

Fig. 14

Figure 15 depicts the insertion of the spatula (f) into the adapter element (c).

To do this first turn the knurled nut (g) anti-clockwise until a sufficient spread of the spatula adapter (c) is achieved so that the spatula (f) can be inserted. Then turn the knurled nut (g) clockwise to clamp the spatula (f) into the adapter.

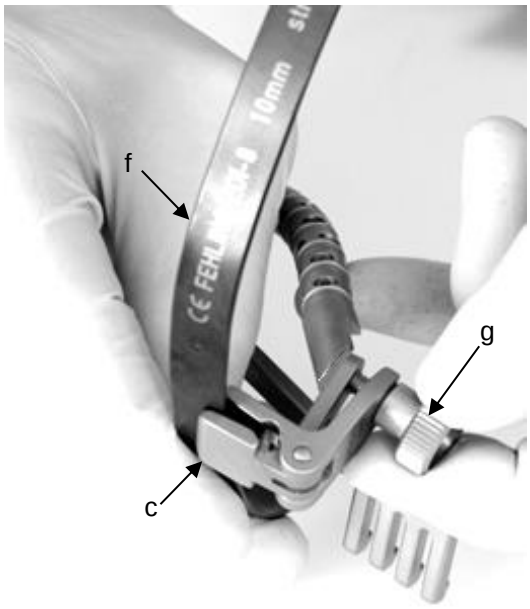

Fig. 15

⚠ Figure 16 depicts an example for the slight bending of the flexible arm (e) required to bring the spatula (f) into the desired position.

Note: The less the flexible arm is bent, the easier and more stable it can be tensioned.

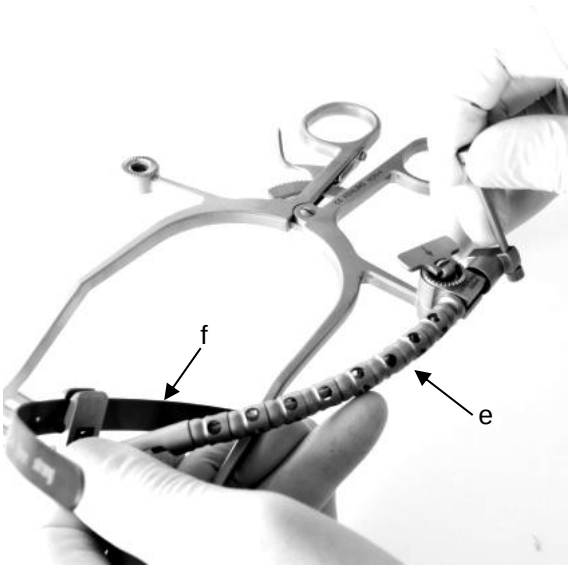

Fig. 16

10) Disassembly

For reprocessing, the flexible arms and spatulas of the CONCEPT CEREBELLAR retractor must be disassembled. Therefore please follow the corresponding assembly instructions (see 9) Assembly).

Please observe the following when disassembling the spatula adapter and flexible arm:

Figure 17 shows a flexible arm with assembly spatula adapter NDN-5.

Fig. 17

To remove the spatula adapter (c) first turn the knurled nut (g) anti-clockwise until it is completely detached from the threaded rod of the flexilble arm (h) (Fig. 18a). Meanwhile compress the spatula adapter (c).

Slowly open the spatula adapter (c) (Fig. 18b) and then remove it from the threaded rod (i) (Fig. 18c).

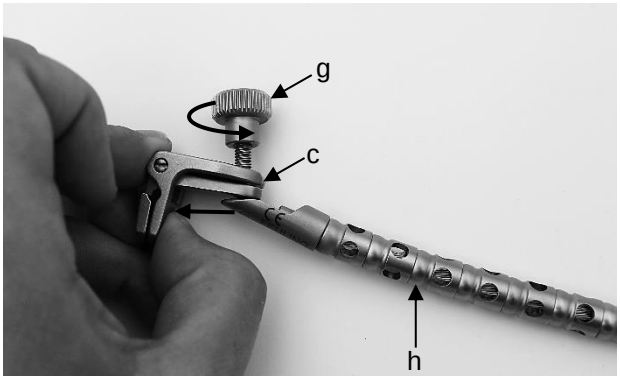

Fig. 18a

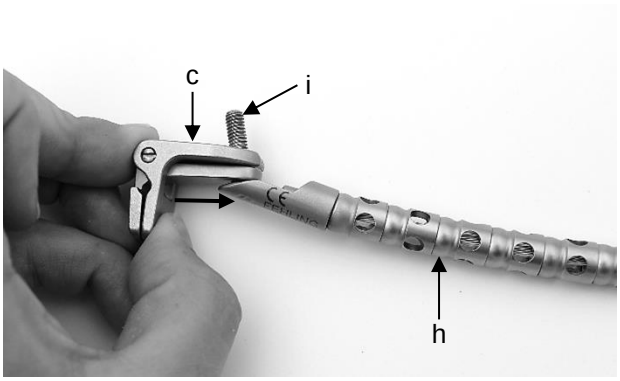

Fig. 18b

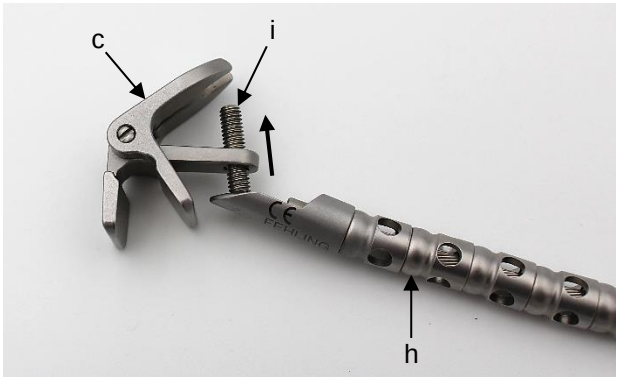

Fig. 18c

The disassembled flexible arm (flexible arm (h) with knurled nut (g) and the spatula adapter (c) can now be reprocessed (Fig. 19).

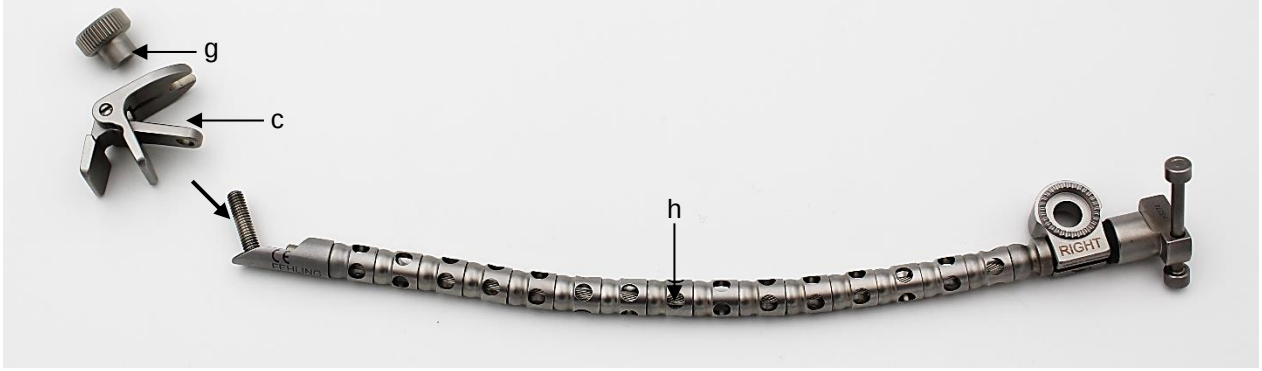

Fig. 19

⚠	Place small parts in suitable containers (e.g. needle boxes) for storage and reprocessing!

11) Obligation to report serious incidents
The user is obliged to report serious incidents relating to the medical device to the manufacturer either per e-mail to vigilance@fehling-instruments.de or via the report form at https://www.fehling-instruments.de/en/complaint/ and the competent authority of the Member State where the user is registered.

Symbols		
In as far as the medical device or medical device label or instructions for use are labeled, according to DIN EN ISO 15223-1 the symbols have the following meaning:		
 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique Device Identifier	 0297 CE labeling
 Oil can for points to be lubricated	 CE labeling	

Contact the manufacturer:		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de	 0297