FEHLING CONCEPT cerebellar (*lat. Cerebellum)* Retractor

Retraction frame NDN-4 CONCEPT cerebellar retractor, frame only, 195 mm

Components

NDO-1.....Clamping arm for CONCEPT cerebellar retractor, 7 segments without spatula holder
NDN-6.....Clamping arm for CONCEPT cerebellar retractor, 8 segments without spatula holder
NDN-9.....Clamping arm for CONCEPT cerebellar retractor, 11 segments without spatula holder
NDO-0.....Clamping arm for CONCEPT cerebellar retractor, 15 segments without spatula holder
NDO-2.....Clamping arm for CONCEPT cerebellar retractor, 21 segments without spatula holder
NDN-5.....Spatula holder for clamping 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 the surgical requirements.

This instrument or medical device is non-sterile when delivered. It is to be reprocessed before use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing.
The CONCEPT cerebellar retractor may only be used, reprocessed and disposed of by qualified medical personnel!
The CONCEPT cerebellar retractor is intended for reuse.

1) Intended purpose

Retractors and retractor components used for short-term invasive surgical procedures are intended to spread or retract various tissue structures, such as skin, bone, muscle, and organs.

Additional information regarding the intended purpose

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

Field of application: Retractors and retractor components are used in all patients where tissue must be temporarily retracted to improve the surgeon's view of the underlying tissue (max. 24 hours).

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

Application environment: Retractors and retractor components must only be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions

2) Indications

Surgical procedures requiring the short-term spreading and retraction of various tissue structures, such as skin, bone, musculature and organs, to access the target anatomical structure. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the retractor and retractor blades used are of the correct size and have adequate stability.

3) Contraindication

Any use that is incompatible with the physical and/or mechanical properties of the specific retractor model is contraindicated. There are no generally applicable contraindications for the use of retractors.
Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying condition. These include, for example, an increased risk of fracture of the bones in osteoporosis.

4) Possible side effects

The following side effects are reported in the medical literature and may also occur during the intended use of retractors:

- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischaemia
- Haemorrhagic infarction or stroke

⚠	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) Before use

FEHLING INSTRUMENTS CONCEPT cerebellar retractor is supplied non-sterile and must be cleaned and sterilised by the user before first use and before each subsequent use (see 6) Reprocessing).

⚠	Perform a safety check before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, inspection and testing").
⚠	Handle the CONCEPT cerebellar retractor with care during storage, transport and cleaning! Avoid impacts and point loading on the CONCEPT cerebellar retractor to prevent any possible secondary damage! Do not overload functional parts!
⚠	Use only intact and sterilised products!

6) Reprocessing

⚠	The medical device is to be reprocessed before use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before 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 mechanical shock and point loading on instruments to minimise causing any secondary damage! Do not overload functional parts.
⚠	Do not clean CERAMO® instruments (recognisable by their black-brown surface) with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these processes leads to the destruction of the titanium-containing CERAMO® coating after some time, due to the leaching of titanium.
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilisation are recommended to activate the shape memory. The following must be observed: • SUPERPLAST instruments must be stored in such a way that the recovery of their straight shape is not hindered by external influences (e.g. other instruments or limited space). • After disinfection/sterilisation, allow the SUPERPLAST instruments to cool to room temperature. Bending the instruments at temperatures above approx. 40°C may impair their function.

Reprocessing limitations	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 labels or marking, functional failure – also see "Maintenance, inspection 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 sterilisation) 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 deionised water (deionised water, demineralised, 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 of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.

Pre-treatment 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 initial treatment 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 before cleaning	Instruments should be reprocessed 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 that were connected to each other during use must be disassembled 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 may be moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush) during the exposure time. • Rinse the instruments for one minute in cold deionised water (see “General Information on Reprocessing”) and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, for preference use a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders.

	When placing instruments in the sterilisation 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 programme: 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 so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the washer/disinfector. <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) <u>Procedure/Parameters:</u> • 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 contamination is no longer visible.

	• Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at < 40 °C with 0.5 – 2% cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • 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. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • 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, inspection 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 sterilisable and steam-permeable is to be applied before sterilisation. 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 compromise the effect of steam sterilisation. Perform a safety check of the instruments before 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 looseness). Check locking mechanisms. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with markings that are no longer legible, must be sorted, cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorised by the manufacturer. A confirmation 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 DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665 (Parts 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 Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, 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. They are to be cleaned before disposal. They can be disposed of 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 result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy 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 that opens and closes according to the scissor principle, as is common and well known in many different variants. Its branches are angled inwards by approx. 30° in the distal area and are each equipped with 4 teeth for the retraction of – mainly – soft tissue. The retraction width can be locked as required up to a maximum of approx. 110 mm using the curved ratchet mechanism.

In contrast to the standard form of the aforementioned scissor retractors, the CONCEPT cerebellar retractor has a laterally, outwardly projecting arm in its middle section with a circular toothed disc at the outer end for mounting a clamping arm.

A multi-segment clamping arm can be connected to each of the two aforementioned toothed discs at any angle by means of a double-toothed adapter. The two, now superimposed, toothed discs are secured by means of a folding-wing screw, which extends through both the clamping arm adapter and the toothed disc of the base retractor. The tension in the clamping arm is generated by an internal steel cable, which is shortened and thus stabilised by a threaded mechanism until the shape/bend required by the user is achieved. The tensioning process is facilitated by a movable lever attached to the proximal end of the clamping arm.

At the distal end of the clamping arm there is a terminal segment that can be rotated 360° around the clamping arm axis. At its distal end, it has a surface angled at approx. 30°, through which a screw with a knurled nut passes at right angles. The screw and knurled nut are used to accommodate a holding element for flat or shaft spatulas.

The spatulas secured by this aforementioned holder are made of shape memory material with a dark ceramic surface. This material allows the spatula to be shaped as required and to return to its original straight form during reprocessing.

Figure 1 shows a configuration example for the CONCEPT cerebellar retractor (1) with the clamping arms (2) and the spatulas (4). The corresponding components are listed in Table 1.

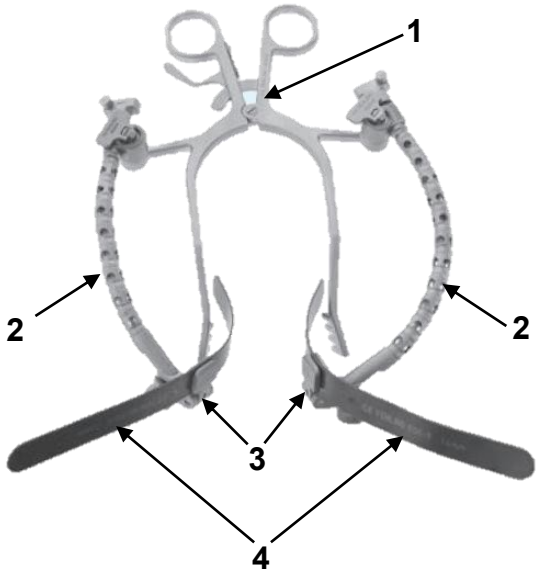

Fig. 1: Configuration example for the CONCEPT cerebellar retractor with the clamping arms, spatula holders and spatulas

Table 1: List of the corresponding components

	Item no.	Description
1	NDN-4	CONCEPT cerebellar retractor frame only, 195 mm
2	NDO-1	Clamping arm for CONCEPT cerebellar retractor, 7 segments without spatula holder
	NDN-6	Clamping arm for CONCEPT cerebellar retractor, 8 segments without spatula holder
	NDN-9	Clamping arm for CONCEPT cerebellar retractor, 11 segments without spatula holder
	NDO-0	Clamping arm for CONCEPT cerebellar retractor, 15 segments without spatula holder
	NDO-2	Clamping arm for CONCEPT cerebellar retractor, 21 segments without spatula holder
3	NDN-5	Spatula holder for clamping arms for CONCEPT cerebellar retractor
4	Select separately	Spatulas in a wide variety of designs

⚠ Use only intact and sterilised products!

⚠	Before using the retractors and the retractor components, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Before using the retractors and the retractor components, ensure that they are fully functional and not damaged!
⚠	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.
⚠	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. Care must be taken to ensure that the retractors and retractor components used have the correct size and geometry, as well as sufficient stability.
During application	
⚠	When inserting the retractor blades, care must be taken not to injure any tissue structures unintentionally (in particular nerves and blood vessels)!
⚠	Excessive and prolonged pressure on the tissue can cause necrosis, ruptures, fractures and other lesions!
⚠	Overloading can cause plastic deformation or fracture of the retractors and retractor components!

Figure 2 shows the CONCEPT cerebellar retractor with clamping arms mounted on both sides in use on a head model.

The tissue surrounding the skull is retracted by the retractor frame NDN-4 (a) for optimal access.

After craniotomy, the two clamping arms (b) with the respective mounted spatula holders (c) and spatulas (d) allow the tissue located inside the cranial cavity to be retracted.

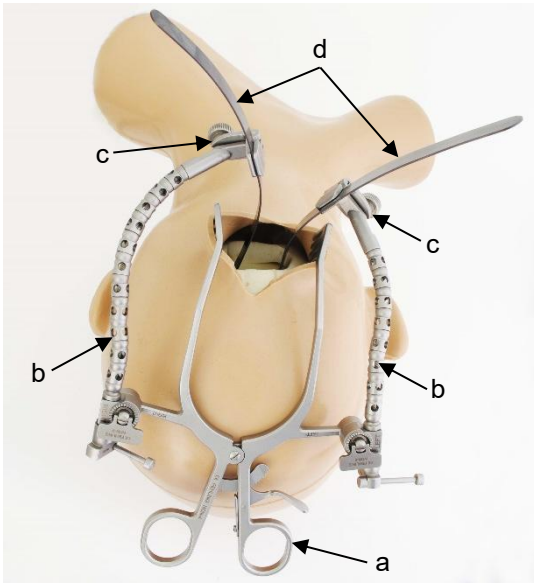

Fig. 2

Figure 3 shows a close-up of the fully assembled and deployed retractor system.

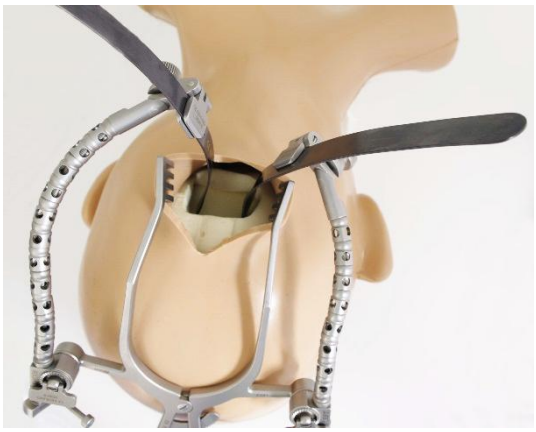

Fig. 3

⚠	Before removing the retractors and retractor components from the surgical field, ensure that the retractor arms are slowly brought back together.

8) Required accessories

No accessories are required for the use of the CONCEPT cerebellar retractor.

9) Assembly

Please follow the instructions below for assembly of the CONCEPT cerebellar retractor.

Figure 4 shows the CONCEPT cerebellar retractor NDN-4 (a) with the clamping arm NDN-6 (b) mounted on the left side with spatula holder NDN-5 (c) and spatula EOI-2 (d).

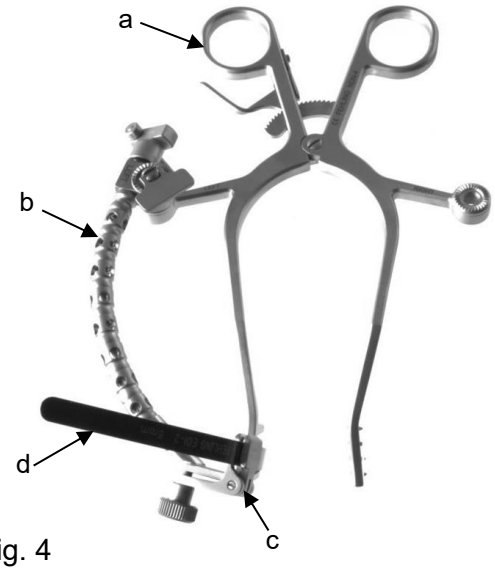

Fig. 4

Figure 5 shows the CONCEPT cerebellar retractor NDN-4 (a) with the clamping arm NDN-9 (e) mounted on the right side with spatula holder NDN-5 (c) and spatula EOI-8 (f).

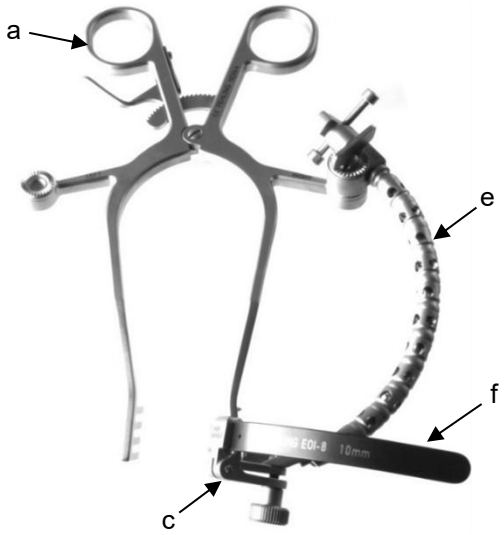

Fig. 5

Figure 6 shows the CONCEPT cerebellar retractor NDN-4 (a) with clamping arms (b and e) mounted on both sides, spatula holders (c) and spatulas (d and f).

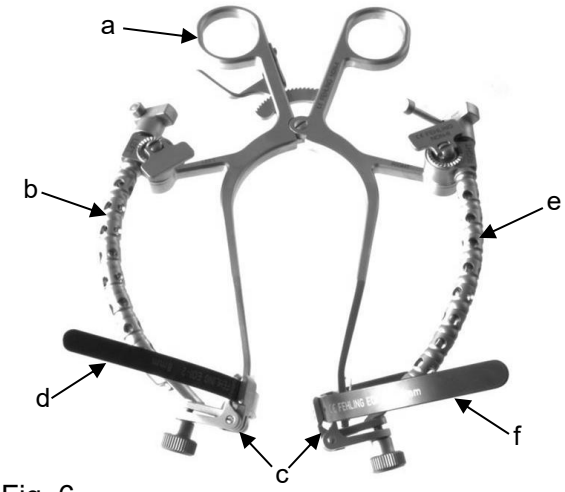

Fig. 6

Attaching the spatula holder to the clamping arm

Before the clamping arm can be attached to the CONCEPT cerebellar retractor, the spatula holder NDN-5 must first be attached to the distal end of the clamping arm. Please observe the following:

Figure 7 shows an example of a clamping arm without a spatula holder.

Fig. 7: clamping arm without spatula holder (example)

To assemble the spatula holder, first turn the knurled nut (g) anticlockwise until it is completely detached from the threaded rod of the clamping arm (h) (Fig. 8). Hold the clamping arm (h) at the same time.

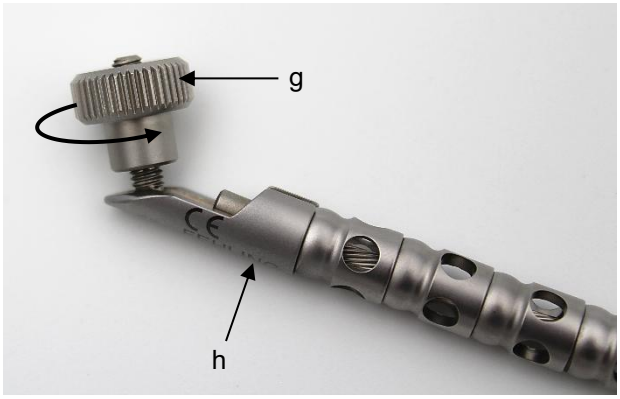

Fig. 8

Figure 9 shows the clamping arm (clamping arm (h) with knurled nut (g)) and the spatula holder (c) disassembled into its individual parts. The spatula holder (c) is screwed tightly between the clamping arm (h) and the knurled nut (d).

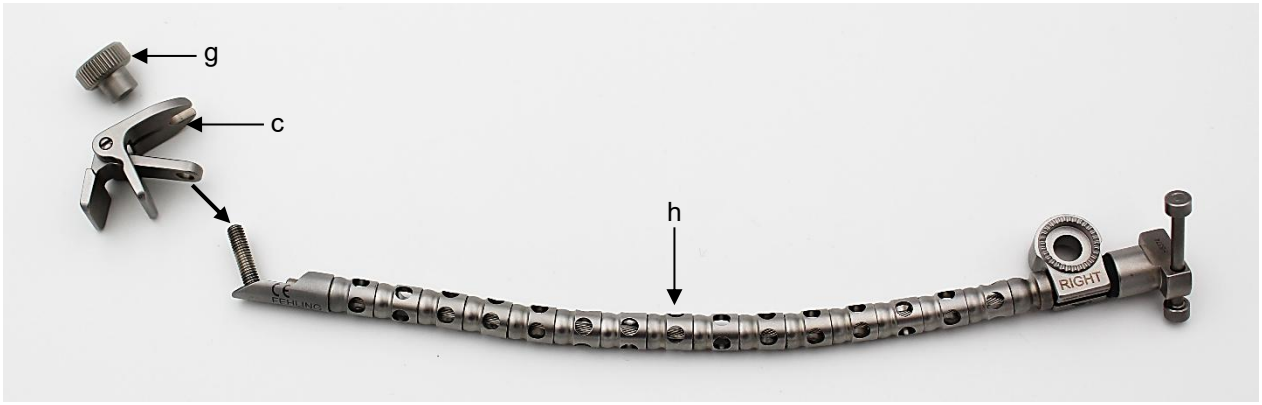

Fig. 9

After removing the knurled nut (g), place the spatula holder (c) on the threaded rod of the clamping arm (h), as shown in Figure 10a.

Then compress the spatula holder (c) (Fig. 10b).

While it is compressed, place the knurled nut (g) on the threaded rod (i) as shown in Figure 10c and tighten it clockwise.

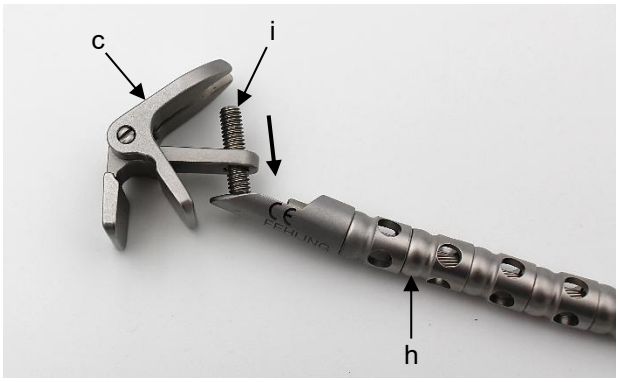

Fig. 10a

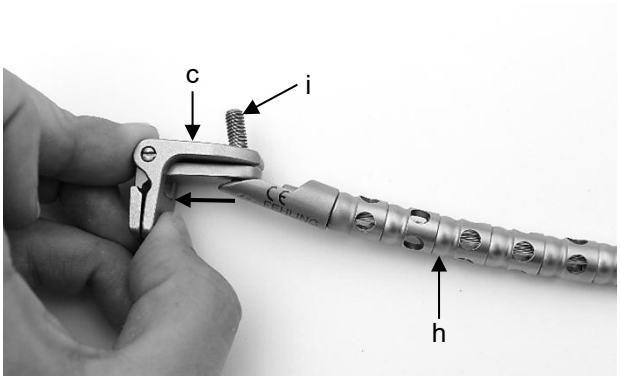

Fig. 10b

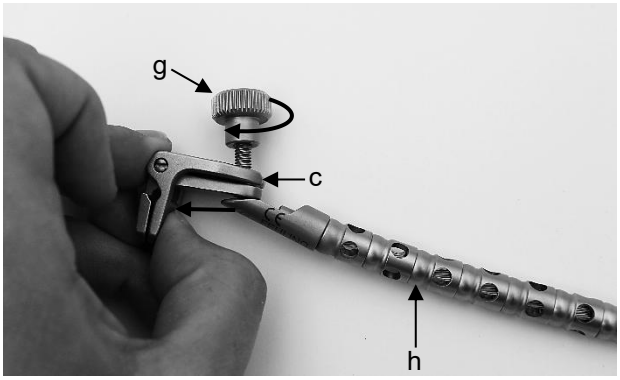

Fig. 10c

Figure 11 shows the clamping arm with the assembled spatula holder NDN-5.
After a functional test, the assembled instrument is ready for use again and can be attached to the CONCEPT cerebellar retractor.

Fig. 11

Assembly of the clamping arms onto the CONCEPT cerebellar retractor

Figure 12 shows the attachment of the clamping arm (e) to the CONCEPT cerebellar retractor (a).

Clamping arms can generally be mounted on the left or right side. This option is possible because there is a toothed profile on both the underside and the top side of the adapter, which engages with the corresponding toothed profile on the top side of the retractor.

⚠ When changing sides, pull the folding-wing screw (k) completely out of the adapter of the clamping arm (e), then turn the clamping arm (e) by 180° and reinsert the folding-wing screw (f). The correct position can be recognised by the fact that the clamping arm (e) is always on the outside of the adapter. There is also a corresponding marking on the clamping arm (e) and the CONCEPT cerebellar retractor (a) (see Fig. 14, page 15).

The distal terminal segment of the clamping arm is connected to the spatula holder at an angle of 30° to its longitudinal axis, and can be permanently fixed or detachable. This terminal segment can be rotated 360° when the clamping arm is not under tension. These two design features, in conjunction with the variable-angle connection of the clamping arm adapter to the retractor frame, allow optimal alignment of the spatulas with minimal bending of the clamping arm.

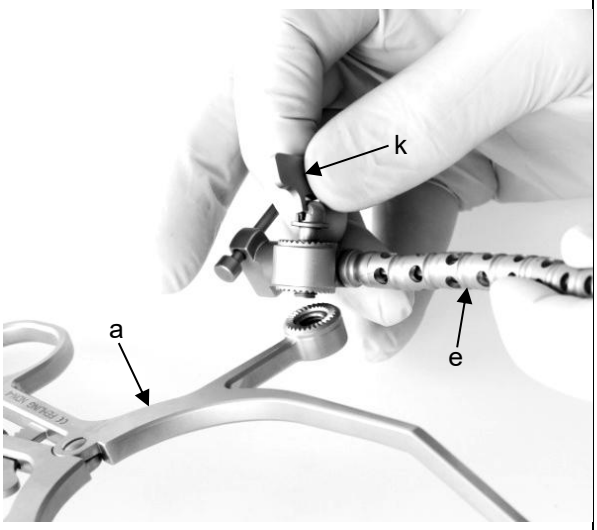

Fig. 12

⚠ Figure 13 shows the maximum position of the clamping arm relative to the retractor frame at which the clamping arm can still be securely fixed (approx. 75°). However, an angle as shown in Figure 13, for example at approx. 90°, would hinder the operation of the clamping mechanism of the clamping arm. (This phenomenon is only relevant for long clamping arms where a large radius can be set, e.g. NDO-2.)

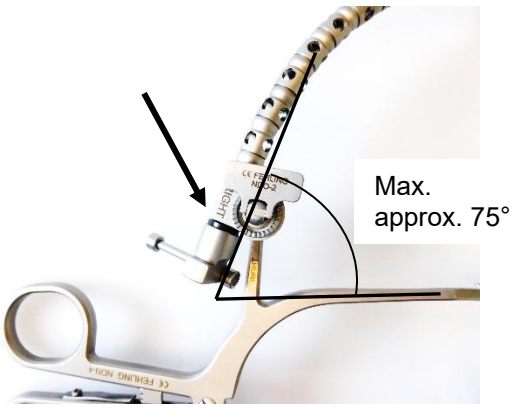

Fig. 13

⚠ Ensure correct orientation of the clamping arms!

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

Marking:
RIGHT – RIGHT
LEFT – LEFT

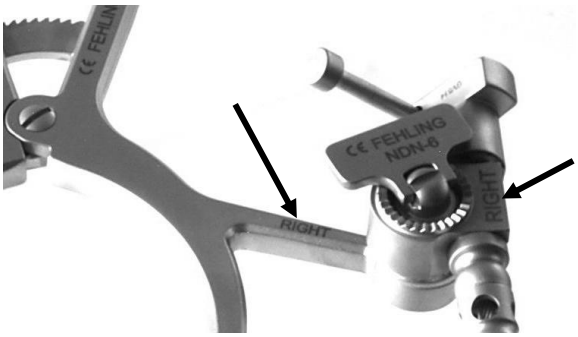

Fig. 14

Figure 15 shows the insertion of the spatula (f) into the spatula holder (c).
To do this, first turn the knurled nut anticlockwise until a sufficient spreading width of the spatula holder (c) is achieved to allow insertion of the spatula (f).
Then turn the knurled nut clockwise to clamp the spatula (f) in the holder.

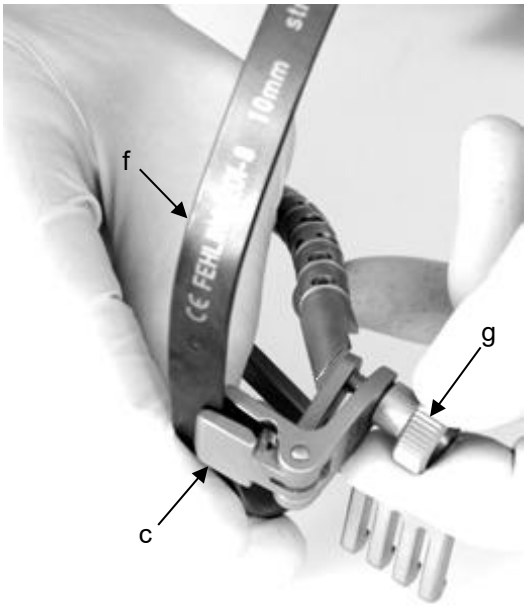

Fig. 15

⚠ Figure 16 shows an example of how the clamping arm (e) can bring the spatula (f) into the desired position with only slight bending.

Note: The less the clamping arm is bent, the more easily and more stably it can be clamped.

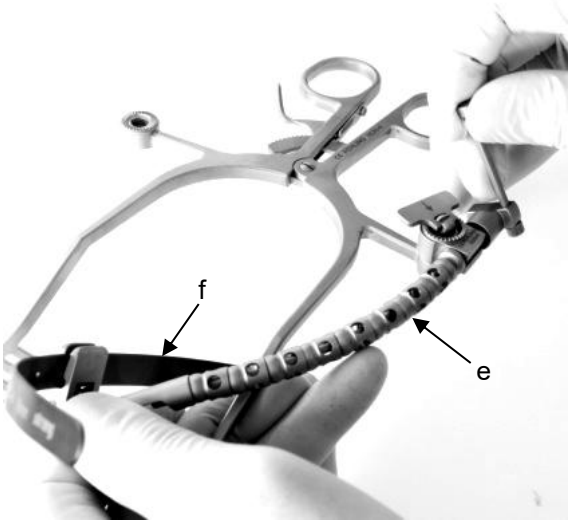

Fig. 16

10) Disassembly

The clamping arms and spatulas of the CONCEPT cerebellar retractor must be dismantled for reprocessing. Please observe the corresponding assembly instructions (see 9) Assembly).

Please observe the following for disassembly of the spatula holder and clamping arm:

Figure 17 shows a clamping arm with spatula holder NDN-5 attached.

Fig. 17

To remove the spatula holder (c), first turn the knurled nut (g) anticlockwise until it is completely detached from the threaded rod of the clamping arm (h) (Fig. 18a). At the same time, press the spatula holder (c) together.

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

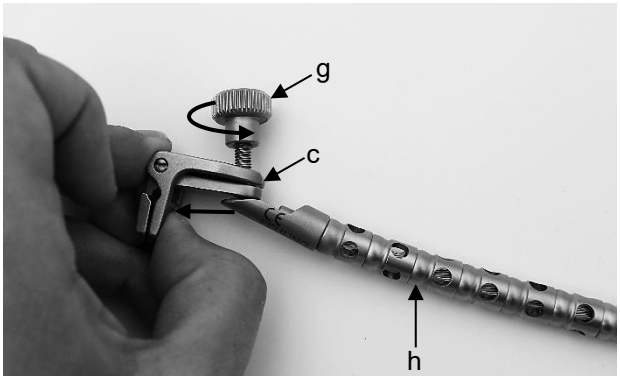

Fig. 18a

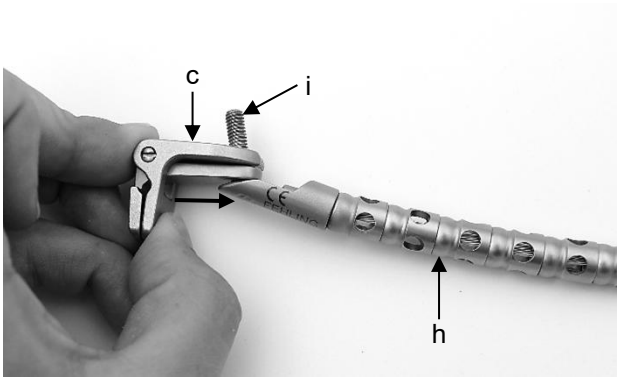

Fig. 18b

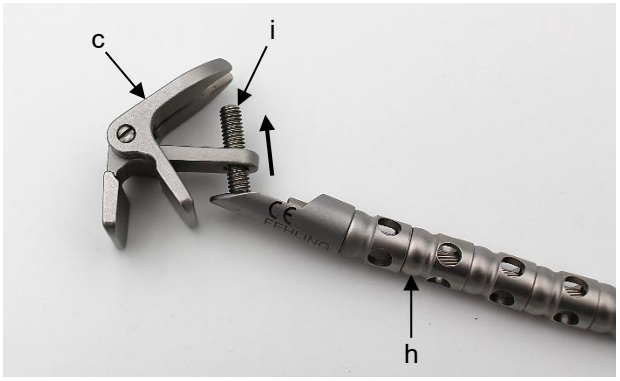

Fig. 18c

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

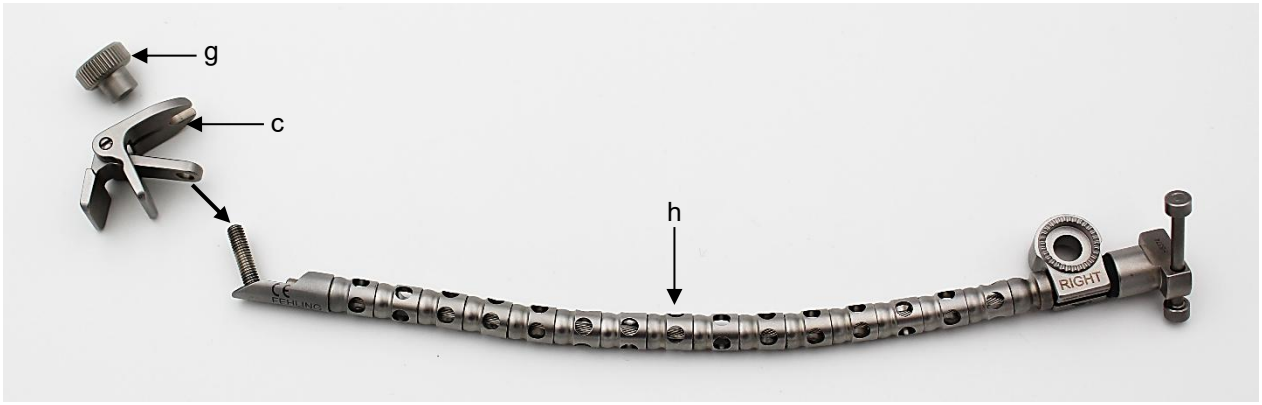

Fig. 19

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

11) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer's contact information		
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