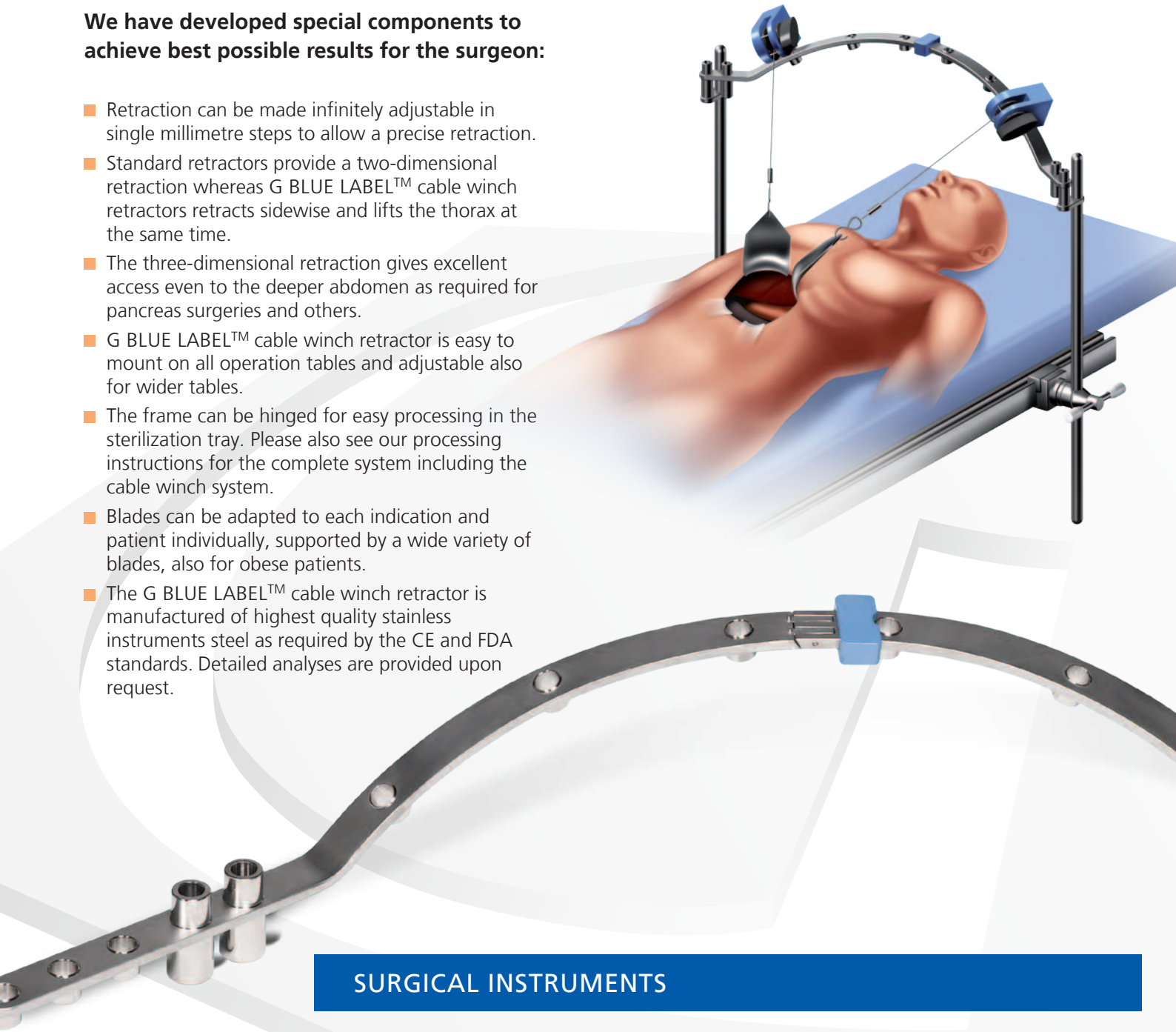
BLUE LABEL

Cable Winch Retractor acc. to Ulrich

The G BLUE LABEL™ cable winch retractor is an abdominal retractor system that allows excellent access for surgeries even in the deep abdomen.

We have developed special components to achieve best possible results for the surgeon:

- Retraction can be made infinitely adjustable in single millimetre steps to allow a precise retraction.
- Standard retractors provide a two-dimensional retraction whereas G BLUE LABEL™ cable winch retractors retracts sidewise and lifts the thorax at the same time.
- The three-dimensional retraction gives excellent access even to the deeper abdomen as required for pancreas surgeries and others.
- G BLUE LABEL™ cable winch retractor is easy to mount on all operation tables and adjustable also for wider tables.
- The frame can be hinged for easy processing in the sterilization tray. Please also see our processing instructions for the complete system including the cable winch system.
- Blades can be adapted to each indication and patient individually, supported by a wide variety of blades, also for obese patients.
- The G BLUE LABEL™ cable winch retractor is manufactured of highest quality stainless instruments steel as required by the CE and FDA standards. Detailed analyses are provided upon request.



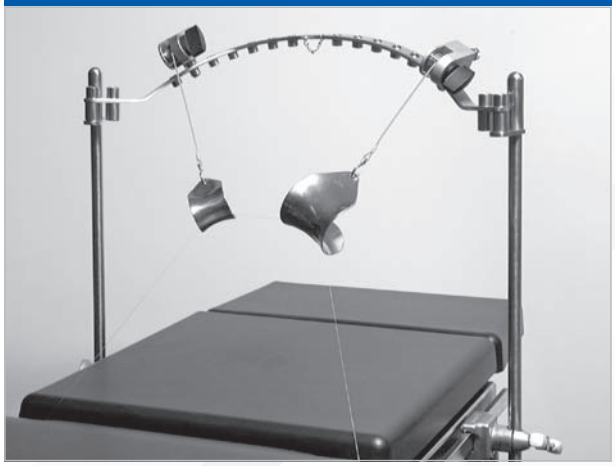
SURGICAL INSTRUMENTS

Product no.
UL7800-00

Attaches to both sides of the lateral bars of the operating table, consisting of

2 x UL7801-09
2 x UL7805-61
2 x UL7807-11
1 x UL7804-63
2 x UL7810-39
2 x UL7811-42
2 x UL7812-55
2 x UL7813-80

Cable winch retractor (University of Ulm)



Length in mm	Length in inch	Width in mm	Depth in mm	Product no.
88	3 ½	63	69	**UL7801-09**

Adjustable

Cable winch system (University of Ulm)

Länge in mm	Length in inch	Outer diameter in mm	Product no.
620	24 ½	2	**UL7801-62**

Spare cable (University of Ulm)

Length in mm	Length in inch	Width in mm		Product no.
630	24 ¾	24		**UL7804-63**
Hinged frame				

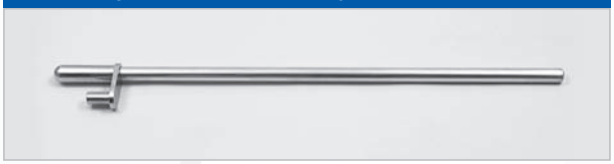
Frame (University of Ulm)

Length in mm	Length in inch	Width in mm		Product no.
800	31 ½	24		**UL7804-63S**
Hinged frame				

Frame (University of Ulm), long version

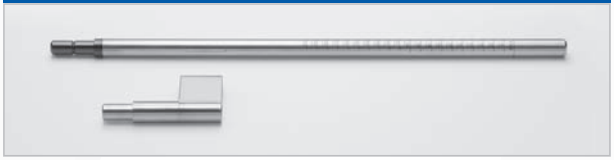
Length in mm	Length in inch	Outer diameter in mm		Product no.
610	24	18		**UL7805-61**

Mounting support (University of Ulm)



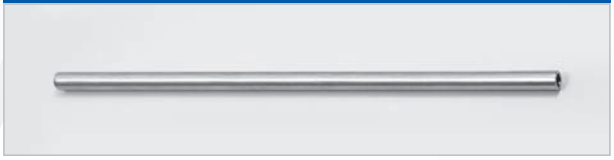
Length in mm	Length in inch	Outer diameter in mm		Product no.
550	21 ¾	18		**UL7805-62**

Mounting support (University of Ulm) dismountable



Length in mm	Length in inch	Outer diameter in mm		Product no.
550	21 ¾	18		**UL7806-55**

Additional mounting support (University of Ulm)



Length in mm	Length in inch	Width in mm	Depth in mm		Product no.
110	4 1/3	70	56		**UL7807-11**

Fixation element (University of Ulm)

Length in mm	Length in inch	Width in mm	Depth in mm		Product no.
70	2 3/4	50	39		**UL7810-39**
75	3	60	42		**UL7811-42**
100	4	80	55		**UL7812-55**

Blade (University of Ulm)

Length in mm	Length in inch	Width in mm	Depth in mm		Product no.
160	6 1/4	50	80		**UL7813-80**

Blade (University of Ulm)

Length in mm	Length in inch	Width in mm	Depth in mm		Product no.
100	4	100	80		**UL7816-60**
135	5 1/3	60	80		**UL7816-80**

Blade (University of Ulm)

Handling information

General

Before each use check the cable winch system for:

- Bent parts
- Correct function
- Any damage, in particular for damage to the surface of the cable winch (if the plastic coating becomes brittle and features cracking, replace cable: replacement cable winch UL 7801-62)

Damaged or defect instruments may no longer be used!

Assembly of cable winch UL7801-62

- Withdraw cable winch completely
- Use allen screwdriver, hex 1.5 mm, to completely unscrew grub screw opposite the black rotary button
- In the same aperture, unscrew the thread with the allen screwdriver, hex 1.5 mm
- Withdraw cable winch

Warning!

- Any use of the instrument not in compliance with its design purpose may lead to the same being damaged or even destroyed.
- Only use original G BLUE LABEL™ accessories

Cleaning and care

- Prepare used systems in the short term
- Clean cable winch system before sterilization. In so doing remove the latching pin (turn by 90°) and unroll cable completely
- Dosing, acting period and acting temperature during disinfection and cleaning in accordance with the instructions of the cleaning agent manufacturer
- Housing is made of Peek; use appropriately suitable cleaning agents
- Use accessories suitable for cleaning
- Do not overload rinsing machines and ultrasonic devices. Avoid rinsing and sonic shadows
- Never use metal brushes or metal pads for manual cleaning
- Rinse carefully after cleaning. If at all possible, use fully desalinated water
- Dry sufficiently after rinsing
- Discard damaged or worn cable winch instruments
- Sterilisation does not replace cleanliness

Sterilisation

- Steam sterilisation at 134 °C

Maintenance and repairs

- All guarantees and warranties will be void if the user or a non-authorized service point carry out any repairs by themselves
- Please send the instrument to our address for any repair and maintenance work
- For reasons of hygiene, instruments sent in for repair must be treated completely

Instrument processing instructions in accordance with ISO 17664:2004 No. B.1

Manufactured by: Geister Medizintechnik GmbH **Medical devices:** Surgical instruments of risk group factor 4

BLUE LABEL

WARNINGS

Do not process disposable devices! The following instructions apply only to devices that are suited for steam sterilization. Do not use additional cleaning agents and avoid harsh manual cleaning. Always comply with the instructions regarding the meticulous mechanical cleaning of instruments.
Avoid throwing or dropping instruments. Delicate instruments must be processed in a tray or mounting device. Avoid incorrect insertion, pressure, loading, propping and bending of instruments.
To prevent damage, never use metal brushes, metal sponges or similar cleaning equipment. To prevent any contact corrosion on stainless steel instruments or on machines, instruments with damaged surfaces must be sorted out immediately.

Use cleaning agents and/or disinfectants with pH values between 4.5 and 12. When using cleaning agents and disinfectants, please comply with the manufacturers' instructions regarding amounts to be used, exposure time and replacement of the solution.

Our devices made of titanium, PEEK and stainless steel are suited for steam sterilization at 134 °C for 18 minutes.

Limitation on resterilization

The number of permitted resterilization cycles or other instructions regarding the end of the instruments' life cycles are specified in the corresponding device descriptions.

INSTRUCTIONS

Use

Before initial use

Remove the instruments from their packaging and remove the protective sheaths and protective wrappers. Before initial use, please read the following additional instructions.

After use

Disassemble the instruments. If they come into contact with corrosive medications or cleaning agents, wash them immediately in water. If there are encrustations on the instruments after cleaning, further chemical treatment is required (e.g. 3% H_2O_2 for 5 minutes).

Dry disposal

Dry disposal can be used for the instruments. Process the instruments as quickly as possible after disposal.

Preparation for decontamination

Wet disposal

The instrument must be completely immersed in a non-corrosive and non-fixing disinfectant bath, whereby the cleaning and disinfectant solutions must be replaced when they are visibly contaminated or at least daily.
Before cleaning, decontamination agents must be removed with water.

Pre-cleaning

If the instrument came into contact exclusively with healthy, intact skin, pre-cleaning is not required.

Ultrasound bath

Open and disassemble the instruments in accordance with the instructions. Flush all cavities with a cleaning and sterilization agent for ultrasound cleaning using a syringe. Use moderate pressure in doing so. Place the instruments in the sieves so that no shadows are formed. Add cleaning agent to the water and adjust the temperature of the solution to comply with the instructions of the cleaning agent manufacturer. The cleaning in the ultrasound bath (35-40 kHz) takes 5 minutes.
Afterwards, flush the instruments, including all cavities, with water and continue immediately with the cleaning and disinfection processes.

Cleaning and disinfection

Mechanical cleaning and disinfection is to be given preference over manual processing.
Open the instruments in accordance with the instructions. Cleaning and disinfection solutions must be replaced whenever they are visibly contaminated or at least daily.

Manual cleaning

Use lint-free cloths, synthetic brushes or water-jet guns for manual cleaning with a non-fixing cleaning agent that is changed daily. Wherever possible, flush the cavities with the cleaning agent with pressure using a syringe, and carefully brush out the cavities. Rinse well with completely desalinated water. Then dip the instrument in disinfectant and use a suitable cleaning tool such as a synthetic brush.
Rinse well again with fully desalinated water from a syringe or water-jet gun and dry the instrument after completion of the rinsing process. Moveable parts must be moved at least 20 times during manual processing.

Automatic cleaning and disinfection unit

Place the disassembled instruments securely in the cart. All cavities must be accessible on one side. Do not overload the cart.
The preliminary rinse is followed by chemical cleaning at 40 to 60 °C. Residues from the cleaning process must be reliably removed in the final rinsing phase. Prevent material degeneration by using neutralization agents. The next step is thermal disinfection at 80 to 95 °C. The final rinsing with completely desalinated water is followed by a drying phase.

Drying

Flush all cavities with 70% ethanol.
The instruments can be dried in a drying oven or with compressed air.

Maintenance, inspection and testing

Let the instruments cool down to room temperature. Inspect them macroscopically for protein residues and other contamination. Instruments which are not clearly free of residues must be subjected to the entire cleaning procedure again. If the instrument consists of moveable parts, apply a biocompatible paraffin oil-based lubricant to the instrument (this does not apply to latex or rubber).
Afterwards you must carry out a functional test corresponding to the specific use of the instrument. Instruments which have spots, are dull, bent, no longer functional or otherwise damaged must be sorted out immediately!

Packaging

The packaging materials must be suitable for the instruments and protect them against microbiological contamination during storage.

Sterilization

Steam sterilization is a required part of these processing instructions. Sterilization accessories (e.g. packaging and storage material) must be adapted to the instruments and the sterilization process. Lock instruments only in the first locked position with the locking mechanism.

Steam sterilization

Load the instruments into the sterilization sieves. Compliance with the recommended total weight limit is required. It is recommended that the sieves be wrapped in towels or fleece and then packed in the corresponding containers or packaged in paper wrappers. Autoclaving must last at least 5 minutes at 134 °C. The instruments must be dried and cooled down to room temperature (23±2 °C).

Storage

After sterilization the instruments must be stored so that they are dry, dust-free and properly ventilated without being exposed to corrosive vapors.

Further information

The quality management system of the processing department must meet the specifications of ISO 13485/13488. Personnel must be trained to process the instruments properly. Steam sterilizers must meet the specifications of DIN 58946. Washing and disinfection units must be validated in accordance with ISO 15883. The packaging material must comply with the specifications of ISO 11607.

Manufacturer's address

Geister Medizintechnik GmbH, Föhrenstrasse 2, D-78532 Tuttlingen, Germany

The instructions given above were validated by the manufacturer of the medical device and are suitable for processing a reusable medical device.
The processor is responsible for ensuring that equipment, material and personnel that can achieve the desired result are employed to perform the actual processing. Usually this requires validation and routine monitoring of the process.