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FEHLING LS distraction and repositioning instruments are supplied non-sterile and have to be cleaned and sterilized by professional staff before initial and every further use (see reprocessing instructions). Test the functionality and surface integrity of the instruments.





Avoid possible root entrapment at the counter-bearing! Risk of injury!





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First, prepare the usual PLIF access. After inserting the pedicle screws remove the inferior intervertebral disc adjacent to the vertebra. It may be necessary to distract the vertebrae (see technical notes) prior to inserting the repositioning instrument

For distraction or repositioning, the distraction jaws a and d of the repositioning instrument must now be placed between the vertebrae with the step b of the inferior jaw pressed against the back edge of the lower vertebra



Care should be taken not to injure the dural sac and the nerve roots.

The counter-bearing **b** of the inferior branch **c** is to be supported at the back edge of the lower vertebra. If it has not already been extended the repositioning slider **e** is moved anteriorly by anti-clockwise rotation of the wrench **j**, or, so that the toothed part of the superior distraction jaw **d** reaches the base plate of the dislocated vertebra. When the toothed part of the superior distraction jaw is in place, close the two handle parts **f** and **g** together and lock them in position by tightening the locking nut **i**.



Care should be exercised that the teeth of the superior distraction jaw do not cave into the base plate of the vertebra.

The instrument must not be operated if the superior distraction plate protrudes by more than 4 cm \rightarrow risk of instability \rightarrow risk of injury!

For reposition of the upper vertebra, rotate the wrench clockwise to pull the repositioning slider posteriorly. As an alternative to the wrench, the knob LCF-0 can also be used for adjusting the repositioning slider.



Care should be exercised not to cause retrolisthesis.



Repositioning instrument, closed



Repositioning instrument, distracted



Repositioning instrument, distracted and reduced

After repositioning of the vertebra the procedure is continued as required (implantation of cages, securing via pedicle screws or similar).



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| Reprocessing instructions | | | | | | | | |
|--|--|--|--|--|--|--|--|--|
| Frequent reprocessing has minimal effect on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use. | | | | | | | | |
| 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. | | | | | | | |
| Storage: | Store the instruments in a dry place in order to avoid condensation. 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. | | | | | | | |
| Cleaning preparation: mechanical cleaning | Disassemble the instrument for reprocessing. Disassembly: Push the repositioning slider e fully forwards by rotating the wrench j anti-clockwise) until this disengages from the threaded rod. Threaded rod. Remove the wrench j and the securing sleeve h from the instrument. Pull off the wrench, the securing sleeve is opened anti-clockwise. Threaded rod | | | | | | | |

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After removing the securing sleeve, pull the threaded rod backwards from the instrument.

| | Threaded rod |
|-----------------------|---|
| | Clean the instruments under running water with suitable soft brushes until no residues are visible. |
| | Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemical manufacturer's recommendation for the dosage). 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. Always reprocess joint instruments open and/or disassembled. If applicable, loosen springs. |
| Cleaning/Disinfection | It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with. If possible, a washer/disinfector which uses thermal disinfection is to be preferred. |
| Cleaning: Automated | Validated presedure: |
| Cleaning. Automated | Equipment: Washer-disinfector G 7836 CD (Miele) |
| | Process: 2-component process alkaline/enzymatic |
| | Detergents: deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland) |
| | Preparation: |
| | • The joint instruments are to be placed in the device such, that the joints are opened and that the water can flow from the cavities and sac holes. |
| | Ensure that the inside of all cavities is also completely rinsed. |
| | Ensure that no unwashed areas are left. |
| | Parameters: |
| | Pre-wash for 3 minutes with cold water Empty |
| | Empty Wash for 10 minutes with tap water with 0.3% TWIN PH10 at 35 °C |
| | and 0.2% TWINZYME at 40 °C |



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| | Empty Rinse for 2 minutes with fully deionized water at at least 30 °C Empty Rinse for 1 minute with fully deionized cold water Empty Perform thermodisinfection for at least 5 minutes at 93 °C After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually. | | | | | |
|----------------------|---|--|--|--|--|--|
| Cleaning: Manual | Validated procedure Equipment: Bandelin Sonorex RK 1028 H Detergents: Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products. | | | | | |
| Disinfection: Manual | <u>Disinfection:</u> Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Deionized water must be used for the final rinse. Ensure that no residues remain on the products. | | | | | |
| Drying: | If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. | | | | | |
| Assembly: | After cleaning, the individual parts need to be reassembled. Proceed in the reverse manner as with disassembly: a) Insert the threaded rod from the back b) Screw on the securing sleeve c) Mount the wrench d) Position the repositioning slider on the threaded rod (from the front) e) Rotate the wrench (clockwise) to draw the repositioning slider back into the handle. | | | | | |
| Maintenance: | Apply a small amount of good-quality, water-soluble instrument spray to the joints. Test functionality. Remove from service any blunt or damaged instruments (check for cracks and damage). | | | | | |





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| Checking and functional testing: | Check joint instruments 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. Remove damaged instruments and send them to the manufacturer for repair. Clear and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer. | | | | |
|----------------------------------|---|--|--|--|--|
| Packaging: | Singly: In accordance with the standard series EN 868 and ISO 11607 Sets: Sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately. | | | | |
| Sterilization: | Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! 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: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes Drying time: at least 10 minutes | | | | |
| Storage: | In accordance standard series EN 868 and ISO 11607 | | | | |
| Additional information: | When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions). Additional national standards like AAMI TIR-12-2004 may be applicable. | | | | |
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The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing 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 and any deviation from these Instructions for Use will result in exclusion of liability!

Subject to change without notice.



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INSTRUCTIONS FOR USE - IFU -



| Storage / Symbols | | | | | | | | | |
|--|--------------------------------------|---------------------------------------|-------------------|-----------------|-------------------|----------|---------|--|--|
| Ţ | | i | REF | LOT | | CE | | | |
| Store in a dry place! | Protect from exces- sive heat! | Follow the instructions for use | Article number | Lot num- ber | Manufactu- rer | CE label | Warning | | |
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