


**Manufacturer**
**Digimed Medizintechnik**

Patrick Mohr

Kreutzerstraße 1

78573 Wurmlingen

Tel: +49 (0) 7461 / 9101172

<http://www.digi-med.de>[info@digi-med.de](mailto:info@digi-med.de)**Products**

These instructions for use are valid for all reusable surgical instruments which are

- are one-piece
- may contain simple joints or
- contain simple moving parts
- may be composed of several exchangeable parts (e.g. handle part and various working inserts)

a precise allocation of the products and product groups can be found in Appendix A.

**Important note**

Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist personnel.



Read the warnings marked by this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.

**1 Scope of application**

The instruments may only be used for their intended use in the medical specialities by appropriately trained and qualified personnel. The attending physician or the user is responsible for the selection of the instruments for specific applications or operative use, the appropriate training and information and sufficient experience for the handling of the instruments.

**1.1 Purpose / Indication**

-See Appendix A-

The instruments from Digimed Medizintechnik must not be used in cardiothoracic and neurosurgery.

**2 Cautions and warnings****2.1 Attention!**

The suction and irrigation instruments are designed for surgical use only and must not be used for any other purpose. Improper handling and care as well as improper use may lead to premature wear of the instruments.

**2.2 Material incompatibility.**

The medical devices should not be used under any circumstances if the user or healthcare professional becomes aware that the patient is intolerant to the material.

**2.3 Functional impairment**

Surgical instruments corrode and their function is impaired when they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilisation instructions.

**2.4 Operating conditions**

To ensure the safe operation of the products mentioned above, correct maintenance and care of the products is essential. In addition, a functional or visual check should be carried out before each use. For this reason, we refer to the relevant sections in these instructions for use.

**2.5 Combinations with other products**

When instruments are reassembled after disassembly, individual parts must not be replaced by parts from other manufacturers!

If parts are interchangeable due to the intended purpose of the product (e.g. various (e.g. different work inserts), parts from other manufacturers must not be used! We recommend, other accessories (e.g. care products) from Digimed Medizintechnik.

**2.6 Storage**

There are no specific requirements for the storage of the products. However, we recommend storing the medical devices in a clean and dry environment.

**3 Liability and warranty**

**Digimed Medizintechnik, as the manufacturer, is not liable for consequential damage resulting from improper use or handling. This applies in particular to non conforming use for the defined purpose or disregard of the preparation and sterilisation instructions. This also applies to repairs or modifications to the product carried out by unauthorised personnel of the manufacturer. These exclusions of liability also apply to warranty services**

**4 Sterility****4.1 Delivery condition**

The medical devices are delivered in a non sterile state and must be prepared and sterilised by the user in accordance with the following instructions before the first and each subsequent use.

**5 Product life cycle**

The products are basically reprocessible. The service life of surgical instruments is only insignificantly influenced by the number of reprocessing cycles performed, if they are carried out according to the validated procedures described here. Rather, it depends on the gentle and careful handling of the instruments in all phases of use, reprocessing, transport and storage. The end of the service life is reached when the prescribed visual and functional inspection reveals signs of wear or defects that restrict the functioning of the product. In this case, the instruments must be marked and excluded from further use and replaced by functional instruments. Furthermore, the end of the use cycle is reached when the clear identification of the instruments is no longer given due to the lack of labelling. The products may no longer be reused,

- if the surface is damaged (e.g. rusting, cracks, sharp edges, etc.)
- if the labelling is no longer legible and traceability is therefore no longer guaranteed
- after treatment of a patient infected with Creutzfeldt-Jakob disease
- if the products no longer fulfil their function.

**6 Preparation****6.1 Warnings**

- Frequent reprocessing affects the quality of the products.
- City water to be used shall comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- The cleaning agents and disinfectants used for validation are specified in these reprocessing instructions. If an alternative cleaning agent and disinfectant (RKI or VAH listed) is used, the responsibility lies with the reprocessor.
- Reassemble disassembled products before sterilisation.

## 6.2 Place of use

The first steps of a proper reprocessing already start in the operating theatre. Coarse soiling, residues of e.g. haemostatic agents, skin disinfectants and lubricants as well as corrosive medicines should, if possible, be removed before the instruments are discarded. Wherever possible, dry disposal (moistened, closed system) should be preferred. Drying of residues must be avoided! Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided with both disposal methods (<6 hours).

## 6.3 Transport

The products must be disposed of dry immediately after use. This means that the products must be transported moist in a closed container from the application site to the reprocessing site so that the products do not dry out.

## 6.4 Preparation for decontamination

If possible, the products must be disassembled before the subsequent reprocessing steps or fed to the further reprocessing steps in an opened state. Rinsing shadows must be avoided. The products must be prepared in suitable sieve baskets or rinsing trays (select size according to product). The products should be fixed in the cleaning basket at a minimum distance from each other. Overlapping should be avoided in order to prevent damage to the products during the cleaning process.

## 6.5 Pre-cleaning

Rinse products under cold city water of drinking quality (<40°C) until all visible dirt has been removed. Remove stubborn dirt with a soft brush. Moving parts on the instrument should be moved. Rinse cavities, lumens, crevices and slits intensively (>60 sec) with cold city water of drinking water quality (<40°C) using a water pressure gun (or similar). Place the products in an ultrasonic bath (<40°C) with an alkaline cleaner (0.5% neodisher® MediClean forte), sonication time of 5 min. and a frequency of approx. 35 kHz. Follow the instructions of the cleaning agent manufacturer. Rinse instruments briefly under cold water (<15 sec). Moving parts must be moved. Rinse cavities, lumens, crevices and slits again each time using a water pressure gun (or similar) (>30 sec.) with cold city water (<40°C).

## 6.6 Cleaning / Disinfection

Proof of the basic suitability of the products for effective machine cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the cleaners Neodisher Mediclean and Neodisher Z. The procedure described below was taken into account. The procedure described below was taken into account Automatic cleaning/disinfection process (washer-disinfector Miele G 7835 CD):

- 1 minute pre-cleaning with cold city water Drinking water quality <40°C

- Water drain
- 3 minutes pre-cleaning with cold city water Drinking water quality <40°C
- Water drain
- 5 minutes cleaning at 55°C±5°C with 0.5% alkaline detergent (0.5% MediClean)
- Water drain
- 3 minutes neutralisation (0.1% Neodisher® Z) with cold city water Drinking water quality <40°C
- Water drain
- 2 minutes rinsing with deionised water <40°C

The special instructions of the manufacturer of the cleaning machine must be observed.

### Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account national requirements for A0-value; e.g. A0-value 3000:

>5 minutes at 92°C±2°C

with deionised water.

### Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector for at least 30 minutes (at 60°C±5°C in the rinsing room). If necessary, subsequent manual drying with a lint-free cloth and blowing out lumens using sterile, oil-free compressed air.

## 6.7 Sterilisation

Proof of basic suitability Proof of the basic suitability of the products for effective steam sterilisation was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the steam steriliser Tuttnauer 3870 EHS serial number 2805203 and employing the fractionated vacuum method. Typical conditions in clinics and medical practices as well as the procedure described below were taken into account.

Sterilisation of the products using the fractionated pre-vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilised in suitable sterilisation packaging.

Sterilisation must be carried out using a fractionated pre-vacuum process with the following parameters:

134°C / 274°F,

≥5 minutes holding time,

3 pre-vacuum cycles

Drying in vacuum for at least 20 minutes The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilisation material must be observed. The autoclave must be installed, maintained, validated and calibrated according to the instructions

## 6.8 Additional information

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and equipment used.

## 7 Function test

Check products after reprocessing and before sterilisation with regard to the following aspects:

- Cleanliness
- Damage, including but not limited to signs of corrosion (rust, pitting), discolouration, deep scratches, peeling, cracks and wear.
- Proper function, including but not limited to sharpness of cutting tools, flexibility of flexible products, mobility of hinges/joints/box locks and moving parts such as handles and ratchets.
- Missing or removed (abraded) part numbers.
- Do not use improperly functioning or defective and excessively worn products, as well as products with unrecognisable markings, missing or removed (abraded) part numbers.

Check products for flawless surfaces, correct assembly and functionality. Do not use heavily damaged products, products with unrecognisable markings, signs of corrosion or blunt cutting edges. Reassemble disassembled products before sterilisation.

## 8. Service and repair

### 8.1 Service and repair

Do not carry out any repairs or modifications to the product yourself. This is the sole responsibility of the manufacturer's authorised personnel. Please contact us if you have any complaints, claims or information regarding our products.

### 8.2 Return transport

Defective or non-conforming products must have gone through the entire remanufacturing process before being returned for repair/service.











## 9 Packaging, storage and disposal

*Standardised packaging of products for sterilisation according to ISO 11607 and EN 868.*

*Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures.*

*Manufacturer's medical devices should be stored and kept in individual packages, boxes or protective containers. Please handle the instruments with utmost care during transport, storage and reprocessing. Maintenance of the sterile state after the sterilisation process must be ensured by the user or the specialist personnel designated for this purpose. The disposal of the products, the packaging material and the accessories must be carried out in accordance with the nationally applicable regulations and laws. The manufacturer does not provide specific instructions for this.*

## 10 Description of symbols used

|                                                                                     |                                      |
|-------------------------------------------------------------------------------------|--------------------------------------|
|  | Attention!                           |
|  | Follow the instructions for use      |
|  | Article Number                       |
|  | Lot designation                      |
|  | CE-mark                              |
|  | Indication for non-sterile product   |
|  | Name and address of the manufacturer |
|  | Medical device                       |

Appendix A (intended purpose): The intended purpose of our instruments is self-explanatory for the user. A precise assignment of the intended purpose can be taken from the table. An assignment (individual to your instrument) can be taken from the declaration of conformity with the article number. This is available on our homepage in the Download tab for the individual products. If you have problems with the download, please contact us directly.

| Product group                                    | Purpose                                                                                                                                                                                                                                 | Contraindication    | Possible complications / side effects / risks |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------------------------|
| <b>cutting_abrasive instruments</b>              |                                                                                                                                                                                                                                         |                     |                                               |
| Plaster saw UMDNS 10-665                         | These active products are used for cutting plaster casts.                                                                                                                                                                               | Not contraindicated | See IFU Chapter 2                             |
| Loop instruments (UMDNS 13-630)                  | These instruments are used to separate tissue.                                                                                                                                                                                          | Not contraindicated | See IFU Chapter 2                             |
| Punching (UMDNS 15-239)                          | Punches are instruments used to remove tissue and bone.                                                                                                                                                                                 | Not contraindicated | See IFU Chapter 2                             |
| Scissors, bandage (UMDNS 13-481)                 | These instruments are used for cutting dressing material.                                                                                                                                                                               | Not contraindicated | See IFU Chapter 2                             |
| Scissors, general (UMDNS 15-245)                 | Scissors are designed to cut tissue, organs, clothing, dressings, sutures and other medical supplies.                                                                                                                                   | Not contraindicated | See IFU Chapter 2                             |
| Scissors eye (UMDNS 13-485)                      | Ophthalmic scissors are used for the general surgical treatment of the eye (without specific indication, e.g. iris scissors, cornea scissors, etc.).                                                                                    | Not contraindicated | See IFU Chapter 2                             |
| Scissors Neurosurgery (UMDNS 13-496)             | Neurosurgical scissors are used, for example, to cut nerve fibres.                                                                                                                                                                      | Not contraindicated | See IFU Chapter 2                             |
| Scissors rectum (UMDNS 13-501)                   | The bowel scissors are used exclusively in operations to cut through the bowel, or to remove parts of the bowel.                                                                                                                        | Not contraindicated | See IFU Chapter 2                             |
| Scissors nose (UMDNS 13-495)                     | Nasal scissors are used to cut tissues and vessels during plastic surgery in the nasal region, such as for deviated septum, in the nasal cavity, or for fractures.                                                                      | Not contraindicated | See IFU Chapter 2                             |
| Scissors Gynaecology (UMDNS 13-493)              | Gynaecology scissors are used to cut tissues and vessels, e.g. when removing the uterus, ovarian cysts or ligating the fallopian tubes for sterilisation.                                                                               | Not contraindicated | See IFU Chapter 2                             |
| Blades for saw (UMDNS 13-449)                    | Saw blades are designed to cut through plaster casts.                                                                                                                                                                                   | Not contraindicated | See IFU Chapter 2                             |
| Saw for bones (UMDNS 13-449)                     | Surgical hand instrument for cutting through bones                                                                                                                                                                                      | Not contraindicated | See IFU Chapter 2                             |
| Saws, general (UMDNS 15-244)                     | Surgical hand instrument for cutting through bones                                                                                                                                                                                      | Not contraindicated | See IFU Chapter 2                             |
| Gouge pliers, disc (UMDNS 15-669)                | Surgical instrument for cutting through bones and bone parts.                                                                                                                                                                           | Not contraindicated | See IFU Chapter 2                             |
| Gouge pliers (UMDNS 13-416)                      | Surgical instrument for cutting through bones and bone parts.                                                                                                                                                                           | Not contraindicated | See IFU Chapter 2                             |
| Chisel, bone (UMDNS 10-825)                      | Surgical instruments used to set bone, remove bone sections or spread bone.                                                                                                                                                             | Not contraindicated | See IFU Chapter 2                             |
| Chisel, general (UMDNS 15-211)                   | Surgical instruments used to set bone, remove bone sections or spread bone.                                                                                                                                                             | Not contraindicated | See IFU Chapter 2                             |
| Knife (UMDNS 15-266)                             | Surgical instruments for cutting tissues, organs, muscles, tendons and medical aids.                                                                                                                                                    | Not contraindicated | See IFU Chapter 2                             |
| Knife handle (UMDNS 12-235)                      | Aids for holding the knife blades, scalpel blades.                                                                                                                                                                                      | Not contraindicated | See IFU Chapter 2                             |
| Cutting instruments, pin and wire (UMDNS 13-041) | A surgical instrument used to cut bone or cartilage tissue during orthopaedic procedures. It consists of two movable blades, usually with ring handles for fingers and thumbs. The distal end of the blades can be of different design. | Not contraindicated | See IFU Chapter 2                             |

| Holding, grasping instruments                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------------|
| <i>Forceps (UMDNS 14-257)</i>                                                                                                                             | <i>A basic set of instruments, they grasp the tissue to be cut, prepared or sutured. Accordingly, they are profiled in the inner surface of the jaws.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp artery (UMDNS 10-865)</i>                                                                                                                        | <i>Clamps are surgical instruments with a locking device which serve to grasp and permanently hold tissues, vessels, surgical material or medical instruments.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp, other (UMDNS 15-212)</i>                                                                                                                        | <i>Clamps are surgical instruments with a locking device which serve to grasp and permanently hold tissues, vessels, surgical material or medical instruments.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp Bulldog (UMDNS 10-868)</i>                                                                                                                       | <i>Clamps are surgical instruments with a locking device which serve to grasp and permanently hold tissues, vessels, surgical material or medical instruments.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp, tube (UMDNS 10-875)</i>                                                                                                                         | <i>Clamping of hoses</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clip, cloth (UMDNS 10-902)</i>                                                                                                                         | <i>Clamping of surgical drapes</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp, intestinal (UMDNS 10-871)</i>                                                                                                                   | <i>A surgical instrument for atraumatic grasping, squeezing, bandaging or holding of the intestine during gastrointestinal interventions</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Clamp, bronchus (UMDNS 10-867)</i>                                                                                                                     | <i>A surgical instrument for atraumatic, compressing the bronchi</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Needle holder (UMDNS 15-726)</i>                                                                                                                       | <i>Needle holders are surgical instruments that hold the needle during surgical suturing.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Forceps, obstetric (UMDNS 11-788)</i>                                                                                                                  | <i>Instrument for grasping and extracting the child via the vagina.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Pliers, bone (UMDNS 15-670)</i>                                                                                                                        | <i>Pliers are mechanical gripping tools. They serve the user to hold, fix bones, tissue and other materials.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Pliers, other (UMDNS 15-221)</i>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Pliers instrument, bone (UMDNS 14-063)</i>                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| Spreading, holding away instruments                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                          |
| <i>Dilator, uterus (UMDNS 11-266)</i>                                                                                                                     | <i>Dilators are used to dilate a canal. Dilators have a rounded tip so that the canal is not injured.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Dilator, other (UMDNS 15-215)</i>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Dilator (UMDNS 11-254)</i>                                                                                                                             | <i>The vascular dilator is a microsurgical instrument for controlled intraluminal vasodilatation.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |
| <i>Speculum vaginal (UMDNS 13-666)</i><br><i>Speculum, ear (UMDNS 13-662)</i><br><i>Speculum, rectal (UMDNS 13-665)</i><br><i>Speculum (UMDNS 15-602)</i> | <i>The speculum is inserted into the vagina during gynaecological examinations, for example. Many specula then allow the two blades to spread so that the vagina can be unfolded. This makes the vaginal skin as well as the cervix visible and accessible. With a speculum it becomes possible to take sterile smears from the cervix or to insert other instruments sterilely into the uterus via the cervix. After the examination, the blades are closed again and the speculum removed.</i><br><br><i>Specula are available in many different sizes to suit the individual anatomical conditions of the patient. The examination can thus be performed painlessly. Other, much smaller nasal specula are used in otorhinolaryngology to view the nasal cavity and nasal passages.</i> | <i>Not contraindicated</i> | <i>See IFU Chapter 2</i> |



|                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |                   |
|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|
| Hook, other (UMDNS 15-225)<br>Tick, other (UMDNS 15-228) | Hooks and hooks are designed to keep the surgical area open as much as possible or to keep delicate tissue aside. Sharp hooks for the subcutaneous tissue, blunt for muscle and fascia, round for the abdominal wall, wide for abdominal organs such as the liver to keep aside and not injure.                                                                                                                                                                                                                                                                                                                                                              | Not contraindicated | See IFU Chapter 2 |
| Retractor (UMDNS 15-242)                                 | To keep the surgical area open as much as possible or to keep delicate tissue aside. Sharp hooks for the subcutaneous tissue, blunt for muscle and fascia, round for the abdominal wall, wide for abdominal organs such as the liver to keep aside and not injure.                                                                                                                                                                                                                                                                                                                                                                                           | Not contraindicated | See IFU Chapter 2 |
| Retractor, self-locking (UMDNS 13-390)                   | Adjustable instrument for different positions. After opening the wound, both blades are inserted and the instrument is fixed in the desired position<br><br>thus providing a free view of the surgical field. Locking devices are available straight or with a curved handle, or with one joint per side, which allows variable bending and does not hinder the surgeon. Fixation is either by lockable latches or by means of a locking screw.                                                                                                                                                                                                              | Not contraindicated | See IFU Chapter 2 |
| Mouth gag (UMDNS 11-822)                                 | Mouth gags, which serve to passively open and hold open the mouth, also belong to the holding instruments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Not contraindicated | See IFU Chapter 2 |
| Spatula (UMDNS 15-249)                                   | Exposing instrument which provides access to the treatment site by lifting, holding away the bones, tissue, nerves and blood vessels.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Not contraindicated | See IFU Chapter 2 |
| Spreader, plaster (UMDNS 13-708)                         | Spreading instrument for opening the plaster casts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Not contraindicated | See IFU Chapter 2 |
| <b>Sterile_storage</b>                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |                   |
| Sterile container (UMDNS 13-730)                         | See instruction manual TD-01-04_A09x01_GA_v1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Not contraindicated | See IFU Chapter 2 |
| Bowl, swab (UMDNS 13-692)                                | See instruction manual TD-01-04_A09x01_GA_v1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Not contraindicated | See IFU Chapter 2 |
| <b>Levering, ablative instruments</b>                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |                   |
| Elevator (UMDNS 11-504)                                  | Hand-guided, manually operated surgical instrument for lifting/separating/stretching/widening (elevation) of bones and tissue.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Not contraindicated | See IFU Chapter 2 |
| <b>Diagnostic instruments</b>                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |                   |
| Probe, other (UMDNS 15-237)                              | They are instruments for palpation, examination and insertion into hollow organs, body orifices, body cavities, natural or disease- or injury-related cavities or pockets in tissue layers. Depending on their type, shape and size, they are intended for diagnostic and/or therapeutic use.                                                                                                                                                                                                                                                                                                                                                                | Not contraindicated | See IFU Chapter 2 |
| <b>Manual rotary instruments</b>                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |                   |
| Drilling instrument (UMDNS 17-760)                       | Instruments for drilling bone and hard tissue                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not contraindicated | See IFU Chapter 2 |
| Screwdriver (UMDNS 13-517)                               | Tool that fits into a screw head and can be used to tighten/loosen/unthread a screw by rotation during a surgical procedure. Usually has a high quality stainless steel shaft, the distal end of which fits specifically into a screw head of approximately the following shapes: Slotted, Phillips (Phillips), Pozidriv (Supadriv), Torx, Hexagonal (Allen), Robertson (Square), Keyhead (Two Pin), Polydrive or Single (Clutch). The proximal end of the shaft may have a handle for manual guidance or a profiled tang that fits into an interchangeable screwdriver handle, manual chuck or motor drive. Some types may include a torque meter. Reusable | Not contraindicated | See IFU Chapter 2 |

|  |                 |  |  |
|--|-----------------|--|--|
|  | <i>product.</i> |  |  |
|--|-----------------|--|--|

*Below you will find an overview of the products for which Digimed provides specific disassembly/assembly instructions incl. reference to the corresponding instructions!*

| <b>Product group</b>                   | <b>Disassembly/assembly instructions</b>                                                                                                                                                                                                                                                                                                                |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Retractor, self-locking (UMDNS 13-390) | <p><i>Please loosen all screws from any valves or sliding shafts.</i></p> <p><i>If possible, all moving parts must be dismantled.</i></p> <p><i>After reprocessing, make sure that the function is checked.</i></p> <p><i>Here, please assemble the parts together. If you have any questions about disassembly or assembly, please contact us.</i></p> |