Information on handling our innovative materials during application and reprocessing

1 CERAMO®

1.1 Properties

CERAMO® surfaces are characterized by great hardness, strong resistance to oxidation and chemical inertia. They are therefore particularly suitable for a large number of clinical applications executed under hospital conditions.

1.2 Application

CERAMO®-coated instruments can be used for all purposes wherever the same or similar instrument models made of stainless steel or titanium without a ceramic surface are used. Compared with these uncoated surfaces CERAMO® surfaces offer the following advantages

- Enhanced resistance to friction (extended service life)
- Greater resistance to oxidation
- Improved antifriction properties
- Reduced reflection of light.

1.3 Reprocessing

For reprocessing of the instruments please observe the user information on reprocessing sterilizable medical devices in accordance with DIN EN ISO 17664-1.

1.4 Warnings

The following should be observed during use:

- The hardness of CERAMO® surfaces protects them from friction but not from plastic deformation. Resistance of a surgical instrument to plastic deformation is determined exclusively by the physical properties of the basic metal. For this reason, instruments with CERAMO® surfaces are also subject to the limitations of the intended use and therefore no warranty is valid in cases of misuse.
- Wherever possible, only have instruments with CERAMO® surfaces repaired by the manufacturer. Repairs by third parties may lead to - sometimes irreparable - damage.

Many instruments with CERAMO® surfaces (e. g. scissors, punches, micro instruments) have their own user information, which is generally provided with the first purchase of these instruments. Please request this user information if you do not have it available.

1.5 Repairs

When used as intended, damage to the instruments is largely excluded. Should damage nonetheless occur - e. g. due to misuse - only the manufacturer can check whether the damage can be repaired and, if technically possible, if repairs can be made. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.

2 PLASMA needle holders

2.1 Properties

Put in simple terms, the PLASMA gripping surfaces of needle holders are a spray ceramic. This distinguished by an

- amorphous surface structure
- high hardness (abrasion resistance)
- chemical inertness (resistance to oxidation).

2.2 Application

In principle, PLASMA needle holders can be used for the same purposes and in the same manner as conventional needle holders with or without tungsten carbide inserts. However, in the interest of the service life of the instruments, the limitations and recommendations described in the warnings must be observed.

Compared to needle holders with conventional gripping surfaces made of hard metal or stainless steel, PLASMA gripping surfaces offer the following advantages

- Enhanced resistance to friction (extended service life)
- greater resistance to oxidation
- free determination of the needle direction.

2.3 Reprocessing

For reprocessing of the instruments please observe the user information on reprocessing sterilizable medical devices in accordance with DIN EN ISO 17664-1.

2.4 Warnings

The following should be observed during use:

- Needle holders and the needles guided by them must always have an appropriate size ratio. For details, please refer to the special user information 'Needle Holders'. Rule of thumb for PLASMA needle holders: the length of the needle should not exceed ten times the width of the gripping surface in the gripping section.
- Do not use PLASMA needle holders for needles intended for piercing bone (e. g. sternal wire needles).
- Never change the position of the needle when the needle holder is closed: the resulting shear forces will damage the PLASMA gripping surface.
- Wherever possible, only have needle holders with PLASMA surfaces repaired by the manufacturer. Repairs by third parties may lead to - sometimes irreparable - damage. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.

2.5 Repairs

When used as intended, damage to the instruments is largely excluded. Should damage nonetheless occur - e. g. due to misuse - only the manufacturer can check whether the damage can be repaired and, if technically possible, if repairs can be made. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.

3 SUPERPLAST/SUPERFLEX instruments

3.1 Properties

SUPERPLAST/SUPERFLEX instruments are made of a shape-memory metal alloy. This is available in two variants:

- SUPERPLAST instruments are plastically deformable at room temperature. This deformability exists in the temperature range between 0 °C and 60 °C, in other words, always within the range of temperatures customary in the OR. The instruments have a shape memory. This is activated at temperatures above 80 °C with the result that the instruments regain their original straight shape. This activation of the shape memory will generally occur during reprocessing.
- SUPERFLEX instruments are super-elastic at room temperature. They deform under load. When the load is removed, the instrument resumes its original shape.

When used as intended, these shape memory properties are retained for an indefinite~~ly~~ period of time.

3.2 Application

- SUPERPLAST instruments are plastically deformed by applying a load, this means that the new shape is retained after the applied load is removed. For deformation purposes, we recommend placing the instrument on the two thumbs side by side, while the two index fingers press on the instrument from the top. Here, it is essential to observe the limits of the bending radius described in the warnings.
- SUPERPLAST instruments such as the probes and spatulas are intended to be shaped to fit the respective anatomical requirements during surgery. Manual reshaping of the deformed instruments after completion of the surgical procedure is neither necessary nor appropriate. Recovery of the straight initial shape occurs automatically during reprocessing.
- SUPERFLEX instruments react super-elastically under external loads. In each case, the instrument dimensions are adapted to the anatomical load specifications. Examples: retractors, probes.

3.3 Reprocessing

For reprocessing of the instruments please observe the user information on reprocessing sterilizable medical devices in accordance with DIN EN ISO 17664-1.

SUPERPLAST/SUPERFLEX instruments can be cleaned and sterilized together with conventional stainless-steel instruments using the same methods. To activate the shape memory of SUPERPLAST instruments, thermal disinfection and steam sterilization are recommended. Please observe the following important notes:

- SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e. g., other instruments or restricted space).
- After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of approx. 40 °C.

3.4 Warnings

The following should be observed during use and reprocessing:

- For the deformation of SUPERPLAST instruments, do not fall below the minimum radii. Rule of thumb: the bending radius must not be less than ten times the material thickness.

  Example: generally speaking, spatulas have a thickness of 1 mm. The permissible minimum bending radius is thus approx. 10 mm.

  Falling below the permissible bending radius influences the shape memory. As a consequence, and although the instrument is still smoothed to some degree during reprocessing, it is no longer possible to fully recover the original straight shape: the result is a slightly bent instrument.

3.5 Repairs

When used as intended, damage to the instruments is largely excluded. Should damage nonetheless occur - e. g. due to misuse - only the manufacturer can check whether the damage can be repaired and, if technically possible, if repairs can be made. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.