Handling Innovative Materials: Their Use and Processing

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 Purpose

CERAMO®-coated instruments can be used wherever the same or similar instrument surfaces of stainless steel or titanium without ceramic surface protection are used. Compared with these uncoated surfaces CERAMO® surfaces offer the following advantages:

- Enhanced resistance to friction (extended useful life)
- strong resistance to oxidation
- improved antifriction properties
- reduced reflection of light.

1.3 Processing

Instruments with CERAMO®-coated surfaces can be cleaned and sterilized by the same methods used when working with uncoated surfaces of stainless steel or titanium unless doing so is restricted by the following cautionary statements.

1.4 Cautionary Statements

The following should be noted when using and handling CERAMO®-coated instruments:

- 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. This is why the rules governing the use of instruments with CERAMO® surfaces are the same as those applying to other instruments and why no warranty is valid in cases of abuse.
- CERAMO® surfaces must not be cleaned with tools containing metals or minerals since such procedures generate concentrated loads that damage ceramic surfaces and reduce their functional and economic value.
- Cleaning agents and disinfectants should only be used at the concentrations indicated by the manufacturer and only for periods not exceeding those specified. If the correct concentrations and exposure times are exceeded surface damage may occur.
- Whenever possible, only the manufacturer should repair CERAMO® -coated instruments. Repairs made by third parties may cause irreparable damage.

Specific user information has been developed for many instruments with CERAMO®-coated surfaces, such as scissors, punches and micro-instruments and is customarily included in the scope of delivery at the time of the first purchase. Please request this information if it has not been made available to you.

2 PLASMA Needle Holders

2.1 Properties

PLASMA gripping surfaces in needle holders are, simply put, sprayed-on ceramic materials characterized by the following:

- amorphous surface structure
- superior degree of hardness
- chemical inertia (oxidation resistance).

2.2 Purpose

PLASMA needle holders are in principle used for the same purposes and in the same manner as conventional needle holders with or without hard metal inserts. But keeping in mind the useful life of the instruments, it is suggested that the restrictions and recommendations found under “Cautionary Statements” be noted.

Compared to needle holders with conventional gripping surface made of hard metal or stainless steel, PLASMA gripping surfaces offer these advantages:

- amorphous surface structure
- Superior hardness (friction resistance)
- chemical inertia (immune to oxidation).

2.3 Processing

Needle holders with PLASMA gripping surfaces can be cleaned and sterilized using the same methods as those used with conventional gripping surfaces of hard metal or stainless steel.

2.4 Cautionary Statements

The following should be noted when using and cleaning needle holders:

- Needle holders and the needles they hold must always maintain the correct size ratio. Details can be found in the specific user information titled “Needle Holder”. The basic rule governing PLASMA needle holders is that needle length should never exceed ten times the width of the gripping surfaces within the gripping area.
- Do not use PLASMA needle holders for needles designed to pierce bone (for example sternum wire needles).
- Never change needle position when needle holder is closed: the shearing strengths thus generated damage the PLASMA gripping surface.
- Always use chemicals for cleaning and disinfecting only at the concentrations specified by the manufacturer and do not exceed prescribed time periods. Exceeding the permissible maximum values regarding concentration and exposure time may damage the treated surfaces.
- Needle holders with PLASMA gripping surfaces should be repaired only by the manufacturer whenever possible. Third party repairs may cause damage that cannot always be corrected.

3 SUPERPLAST/SUPERFLEX Instruments

3.1 Properties

SUPERPLAST/SUPERFLEX instruments are made of a metal alloy with shape memory. Two variants exist:

- SUPERPLAST instruments can be deformed at room temperature. Under the effect of ambient temperatures above 80° C (washing machine, autoclave) intraoperatively deformed instruments return to their initial shape.
- SUPERFLEX instruments are superelastic at room temperature. Under a load they are deformed. When the load is removed the instrument returns to its original shape.

The properties of shape memory are retained for an unlimited time if the instruments are used for the purposes for which they are intended.

3.2 Purpose

- SUPERPLAST instruments are plastically deformed when exposed to loads, which means that after removal of the load they retain their new shape. Recommended for inducing deformation: the instrument should be placed on two thumbs held parallel to each other while both index fingers press against the instrument from above. It is absolutely necessary that the limits of the bending radius as described under “Warning” be observed.

  SUPERPLAST instruments may be repeatedly deformed during surgery. To return the instrument manually to its original shape after surgery is neither necessary nor does it serve any purpose. The instrument will automatically return to its straight initial shape during cleaning/sterilization.
- SUPERFLEX instruments react with superelasticity to applied exterior force. Instrument dimensions are in every instance adapted to the given anatomical pressure data. Examples: spreaders, probes.

3.3 Processing

SUPERPLAST/SUPERFLEX instruments may be cleaned and sterilized together with conventional stainless steel instruments using the same technique. Steam sterilization is recommended to activate the shape memory of SUPERPLAST instruments. The following is important:

- SUPERPLAST instruments must be arranged so that the return to their straight shape is not inhibited by environmental factors, such as proximity of other instruments or tight spaces.
- After sterilizing allow instruments to cool to room temperature.

3.4 Cautionary Statements

The following should be noted when using and handling the instruments:

- When deforming SUPERPLAST instruments it is imperative that nothing smaller than minimum bending radiuses are used. Basic rule: the bending radius must never be less than ten times the material thickness. Example: the thickness of a coronary probe is about 0.8 mm at a distance of about 30 mm from the distal tip of the probe. This permits

a permissible minimum bending radius of 8 mm, corresponding to an arc diameter of about 16 mm. Or: Brain spreaders are usually 1 mm thick. Thus the permissible minimum bending radius is about 10 mm. Remaining below the permissible bending radius affects shape memory. The result is that during cleaning/sterilizing the instrument will still straighten but a complete return to the straight original shape can no longer be achieved: one ends up with a slightly bent instrument.

- If used correctly as intended, damage to the instruments is largely avoided. Nevertheless, if damage occurs – perhaps caused by abuse – only the manufacturer can determine whether it can be corrected and make repairs to the degree it is technically possible.

4 Conclusion

The important basic rule that applies without reservations: User information and statements urging caution are useful only if they are made known to personnel within the framework of good hospital organisation and if adherence to rules is regularly monitored.

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