USER INFORMATION

EN 02-10/25

For the application and reprocessing of malleable instruments with and without CERAMO® surfaces

Malleable instruments made of steel or titanium

ATTENTION: For malleable instruments made of NiTi (SUPERPLAST and SUPER-FLEX), consult User Information A01.

1.1 Application

- Malleable 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.
- Malleable instruments can be deformed several times intraoperatively. However, as every reshaping leaves molecular traces, reshaping should be limited to the absolute necessities.

Reprocessing

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

1.3 Warnings

The following should be observed during use and reprocessing: for the deformation of malleable instruments, do not fall below the minimum radii. Rule of thumb: the bending radius must not be less than ten times the material thickness.

1.4 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.

2.1 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.



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2.2 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.

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:

- 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.

2.5 Repairs

When used as intended, damage to the instruments is largely excluded. Should damage none-theless 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.