



Content

Validity	1
EG-Certificate of Compliance	1
Preface	2
Delivery check	2
Material	2
Implant Steel	2
Titanium:	2
Labeling and packing	2
Storing	2
General information	2
Users	2
New implants	2
Sterilisation	2
Pretreatment	2
During the operation	2
After the operation	2
Reuse of implants	2
Risks for special groups	2
Guaranty	2
Literature	2

Validity

This manual is valid for the following SCHREIBER Products:
 Bone wires, -nails, -screws, plates and -pins, distributed by SCHREIBER GmbH. General information can be found in the SCHREIBER "manual for standard instruments".

Certificate of Compliance

In accordance to the MDD Directive 93/42 EC Annex II

Manufacturer's name and adress:

SCHREIBER GmbH
 Chirurgische Instrumente
 Unterer Damm 15
 D-78567 Fridingen

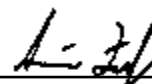
Produkt names:

Skeleton implants, class IIa und IIb, according to the valid catalogue and price lists.

The above mentioned products comply with the requirements according to annex II section 3 of the council directive 93/42/EEC. These products are permitted to carry the CE 0483 -mark.

We have established a certified quality management system according to DIN/EN/ISO 13485:2003

Signature



 Armin Zepf
 Quality Manager

Preface

With purchasing this device you have made a decision in favour of a high quality instrument. To guarantee its proper function and safety for a long time, the following points should be observed carefully. SCHREIBER implants are delivered in non-sterile condition and must be cleaned and sterilized before use.

Delivery check

All products must be checked after receiving immediately on transportation damages or other faults. Compensation can only be claimed, if the shipper or dealer are informed immediately.

Material

Implant Steel

These Implants made of vacuum melted, pure chrome-nickel-molybdenum stainless steel according to DIN 17443 and ISO 5832-1 compound D, Grade B, (AISI 316 LVM) ASTM-F 139 grade, distributed by SCHREIBER GmbH.

The surface of these implants is chemically passive, i.e. it is not magnetic. These implants can be combined with standardized chrome-nickel-molybdenum stainless steels as far as their composition correspond to the analysis determined in DIN 17443 and ISO 5832-1 compound D, Grade B, (AISI 316 LVM) ASTM-F 139 grade. For the permissible dimensions consult the corresponding DIN or ISO (ASTM) standards.

Titanium:

These implants are free of any alloys. Titanium is biocompatible and has been successfully used by the AO Group since 1966. Implants and prostheses made of titanium cannot be combined with implants made of stainless steel.

Labeling and packing

Bone screws are packed in single or multi boxes. Other implants as nails or plates are packed individually. The label on the packing gives all necessary information about the content.

Storing

Implants should be stored under dry and dust-free condition at 15-35 °C, There should be no chemicals in the near surrounding.

General information

We want to point to the fact, that implants can fulfill their destination only, if the following points are observed:

Implants and fixateurs must be chosen under observance of the patients weight, activity grade and the type of the fracture. It is very important, that the forces between implant and body are kept as low as possible by a suitable selection of the

bio-mechanics.

Strong deforming of implants must be avoided. Starke Verformung der Implantate ist zu vermeiden. Careful bending of plates, nails and wires does not lead to damages.

Multiple bending must be avoided absolutely.

The reuse of implants is not allowed. We recommend to inform the patient about risks and disadvantages of implants, before operation.

Implants have a limited strength. Overloads of the implants caused by the patient's body weight must be avoided. Ignoring of this warning can have serious consequences.

Users

Implants should only be used by special employed persons. The surgeon must be able to use the implants according to the national standards for osteosynthesis products in cooperation with the generally accepted training and literature.

New implants

All Implants should stay in their packing until sterilisation. They should be unpacked just before cleaning. It is necessary to wash implants before use. The surfaces are treated with special procedures to reach a high purity (i.e. electro-polishing). This cleanliness cannot be guaranteed after packing and handling. The manufacturer takes special care on these procedures, but it is nevertheless necessary to wash and disinfect all implants before sterilisation. After Implants have been taken off their packing, they must be treated the same way as contaminated ones. Gloves are recommended to avoid mechanical damages of the surface. New implants can be sterilised according to the usual directives. All part must be checked for suitability.

Sterilisation

Autoclave sterilisation is recommended. Flash sterilisation or sterilisation with chemical additives is prohibited. (see EN 554 and manual of the autoclave manufacturer)

Pretreatment

All sterile implants and the needed instruments must be prepared after the pre-operation planning before the operation.

During the operation

Keep implants covered until they are needed, to avoid contamination. Touch the needed implants only. Handling implants should be reduced to a minimum, otherwise surfaces can be damaged.

Use stencils when plates must be bent, to avoid corrections.

After the operation

Contaminated implants must be separated and washed by hand and rinsed with demineralized water. For drying a dry duster can be used. Cannulated implants and screw slots must be blown out with compressed air. deformed bending stencils can be rebent to their original shape.

Reuse of implants

If implants are removed from a body, they must not be used again. Unused implants can be cleaned and packed again. Screw and Plate boxes must be cleaned with alcohol. If they are contaminated, a full cleaning process is necessary. Cleaning should be carried out by hand to avoid damages. Drying can be made in the autoclave before packing for sterilisation.

Filling:

Avoid touching the implants or use gloves. To keep small plates together, they can be tied with a stainless steel wire. Do not stack up.

Risks for special groups

The surgeon has to find out the dimension of the injury, that make an operation necessary. Especially the correct operation procedure must be fixed. This is very important, when the patient has one of the following complaints.

- Illness
- Osteoporosis
- Infections
- Drug addiction
- Epilepsy
- Senility
- Overweight

With complex multi fractures it is also very important to choose the best moment and osteosynthesis technique.

Guaranty

We give 10 years guaranty on material and manufacturing faults.

The SCHREIBER GmbH does not assume any liability, if the user is provable offending against this manual.

Literature

-Knochenbruchbehandlung, Empfehlung des Gerhard-Küntschler-Kreises, V. Vécsei et al - Georg Thieme Verlag 1995.

-FMT-Fachwissen Medizintechnik, Folge 3: Instrumente in der Medizin, Knochenchirurgie, Klaus Witzer -MTD-Verlag Amtzell, 1991

-AO-Instruments and Implants, R. Texhammar, C. Colton, Springer Verlag, 1995

worked out by Armin Zepf QMB, changes and printing errors reserved