# Instruction of use

Surgical saw blades

REF 60-500-08 AO - 60-714-127 HA

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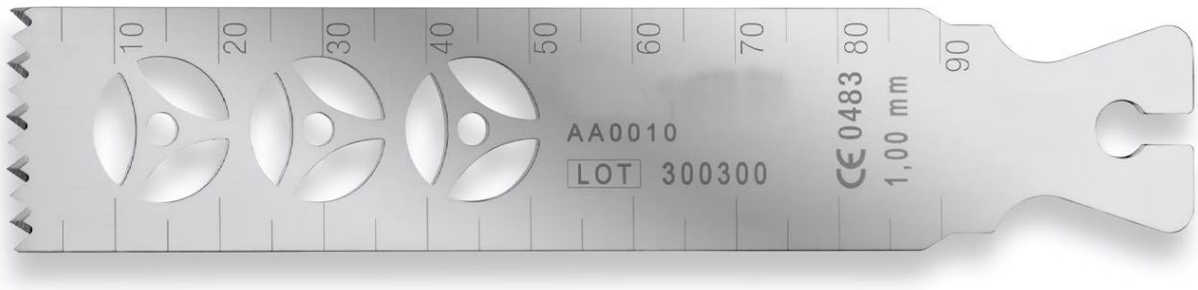


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## 1. Intended use / Indication

The saw blades are used for sawing, cutting bone (bone material), resection of the femoral head, distal femoral condyles, proximal tibial plateau. Preparation of various osteotomies on large and small bones of the upper and lower extremities (e.g. distal/proximal femoral and tibial head osteotomies, humerus protection, calcaneus osteotomies, osteotomies for repositioning).

**Caution! - Warning notice**
The product may only be used by appropriately trained and qualified personnel. Before using the product, it must be ensured that the instructions for use have been read and understood in full or that the users have been adequately trained and that the warnings have been observed.

If, in the opinion of a qualified surgeon, the use of the products could endanger the patient, e.g. due to the general condition of the patient or if the method as such represents a hazard, the use must be refrained from. The same applies if users or third parties are at risk.

**Contraindications**

A direct, immediate contraindication in connection with saw blades is only due to the contraindication associated with the surgical method. In the course of the procedure, the use of bone saws in osteoporosis can lead to splintering at the cutting edges.

**Caution! - Warning notice**
Saw blades, like all medical products or surgical instruments, should always be handled with the utmost care during transport, cleaning, care, sterilisation and storage.

The products are supplied non-sterile. Products supplied non-sterile must be reprocessed before use.

## 2. Inspection of the products

**Caution! - Warning notice**
Combinations of medical devices are only considered safe if
- these are labelled as such in the respective instructions for use, or
- the intended purpose and the interface specifications of the products used in combination permit this.

The saw blades must be checked for any damage and their function immediately upon receipt and always before use.

Particular attention should be paid to the following points:
- Is the packaging damaged?
- Is the surface damaged or corroded, cracked?
- Is the shaft or tip(s) (working end without chipping) undamaged and in perfect condition?
- Are the holders (connections) in perfect condition?
- Is the product straight (risk of deformation)?
- Can the product be inserted correctly and securely into the holder?

**Caution! - Warning notice**
If there are signs of damage, the saw blades must not be used under any circumstances!
Damaged products must not be repaired by the user.

All saw blades are correctly prepared at the factory for their subsequent use. Therefore, any manipulation such as readjustment or rebending is strictly prohibited, as this may impair the operational safety of the saw blades and pose a potential risk to users and patients.
AS Medizintechnik GmbH recommends using or combining only original AS Medizintechnik GmbH products and accessories, as only these are optimally matched to each other and guarantee safe and flawless function and use.

In the event of non-compliance, AS Medizintechnik GmbH cannot accept any liability for any damage that may occur.

## 3. Inserting the saw blades

The size and dimensions must be matched by the doctor to the corresponding application/indication. The holder and the shaft must be compatible with each other.
The shaft is now inserted into the holder and secured. Ensure secure locking or tight fit / fixation.
Only use saw blades that have the same connection system as the holder.

## 4. Application - proper use

Please note:
- Ensure that the saw blades are securely fixed in the holder.
- Only use the saw blades when the working area is in your field of vision and the desired contact has been established.
- Electromagnetic interference from other devices, especially pacemakers, may occur when using electrosurgical devices.

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- During use, care must be taken not to tilt, lever, manipulate or bend the saw blade - risk of breakage.
- Avoid contact of the saw blade / cutting edge with guides or templates. Contact can damage the saw blade and impair its proper function.
- The saw blades must be checked for sharpness after each use. If the sharpness is no longer guaranteed, the saw blade must be replaced with a new one.

**High contact pressure warnings:**
Avoid high contact pressures. The consequences of high contact pressures are
- Damage to and chipping of the saw blade teeth
- Reduced service life of the saw blades
- Excessive contact pressure or the use of a blunt saw blade can lead to thermal damage to the bone tissue and bone cells (necrosis). This can lead to impaired osteogenesis.

## 5. Configuration of the saw blades

To ensure that the saw blades function properly, the product must be combined in the system intended for this purpose (handpiece, saw block, etc.).

## 6. Reprocessing (cleaning, disinfection and sterilisation) of products

You can find information on preparation in the following document: AU_100_EN_Master reprocessing instruction

## 7. Packaging

After cleaning and disinfection, the instruments must be transferred to packaging suitable for sterilisation.

## 8. Inspection and maintenance

Allow the products to cool down to room temperature.
Check the individual parts for damage or deformation when disassembled.
The products must be assembled for a functional test.

## 9. Storage

Transport and storage must not adversely affect the properties of the reprocessed medical device. The storage period and shelf life are determined by the user.
The products must be handled and stored with care. Damage or scratches can significantly impair the strength and fatigue resistance of the product.

According to the recommendation of the DGSV® e.V. (German Society for Sterile Supply), the products should be stored as follows:

- dry
- Dust-protected / low-dust
- Protected from light
- Protected from damage and mechanical influences
- at room temperature (max. 25° C)
- Protected from extreme temperature fluctuations
- Separated from non-sterile product tens
- clean and free from vermin

## 10. Disposal

**Risk of infection!**
The product or parts of it may be contaminated after use. Clean and disinfect the product before disposing it.

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws.
The country-specific laws and regulations must be observed for disposal.

## 11. Reporting of incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Please report serious incidents and occurrences to the manufacturer immediately without delay. A corresponding reporting form can be found on our homepage (www.AS-Medizintechnik.de) in the media centre.

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## 12. Warranty

AS Medizintechnik GmbH is only responsible for ensuring that each individual product has been manufactured, inspected and packaged with the greatest possible care. As AS Medizintechnik GmbH has no influence or control over indications and/or applications, AS Medizintechnik GmbH cannot be held responsible for complications or the failure of an application. AS Medizintechnik GmbH individual products and sets are compatible with each other. Nevertheless, the user is requested to ensure that the products are compatible with each other before use. This applies in particular if the user uses AS Medizintechnik GmbH products in conjunction with products from other manufacturers. Employees of AS Medizintechnik GmbH are not authorised to modify the aforementioned conditions or to extend liability or to enter into additional product-related obligations.

## 13. Explanation of symbols

| Symbol | Explanation |
|---|---|
| | Manufacturer |
| | Production date |
| REF | Order number |
| LOT | Batch number |
| SN | Serial number |

| Symbol | Explanation |
|---|---|
| | Observe user manual |
| | ATTENTION |
| NON STERILE | Non-Sterile |
| | Keep away from sunlight |
| | Protect from moisture |

| Symbol | Explanation |
|---|---|
| GS1 | GS1 Germany |
| MD | Medical device |
| QTY | Quantity |
| UDI | Unique Device Identification |

| Symbol | Explanation |
|---|---|
| CE 0483 | CE marking with Number of the Notified Body |

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