

# Instruction of use

Flexible  
intramedullary reamers



CE 0483



AS Medizintechnik GmbH • Sattlerstrasse 15, 78532 Tuttlingen, Germany • Tel 07461/966326 • Fax 07461/9663288

**Before using the intramedullary reamer, please ensure that it is functioning properly and free of any defects. In addition, please follow these instructions, including the information regarding repair as well as the safety information. This will ensure that no damage results from incorrect assembly or operation, which are not covered by guarantee and for which the manufacturer shall not be liable.**

The intramedullary reamer is not to be operated and used only by persons who have the necessary training and technical knowledge to do so. We reserve the right to modify our products and their technical specifications without prior notice. Please keep these instructions for future reference. They must be available to operating room personnel.

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## 1. Overview

- Drill head
- Flexible drill shank
- Shank

## Explanation of symbols

Allways follow the instructions in the manual  
CE-marking according to directive = CE 0483  
93/42 EEC Annex II.3

## 2. Purpose

The purpose of the intramedullary reamer is to drill an intramedullary socket prior to the insertion of implants (e.g. intramedullary nails, hip endoprostheses).

## 3. Mode of operation

The intramedullary reamer is used to drill intramedullary sockets in a stepwise manner until the desired final diameter is reached.

## 4. Hazards and warnings

There is a little risk to personal safety incurred, through the use of the intramedullary reamer. Nevertheless, incorrect operation or misuse can be hazardous :

- for the user
- for the patient
- for the unit

All persons who operate this tool should read carefully the following information regarding safe use. Your safety is at stake.

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## 4.1 For the user Warning

Injuries, as well as irreparable damage to the reamer can result if it is operated in a counter-clockwise (left-hand) direction. The intramedullary reamer should only be operated in a clockwise (right-hand) direction.

### Warning

The use of the guide spindle that is excessively curved or warped, and/or excessive bending of the intramedullary reamer, can lead to increased friction and thereby to unintentional removal of material from the guide spindle and thereby to binding of the drill. Only guide spindles and intramedullary reamers should be used whose surfaces are undamaged and free of defects and whose shanks are not warped.

### Caution

The intramedullary reamer is delivered unsterilized. It must therefore also be sterilized prior to initial use (see section 9).

### Caution

In order to avoid accidental operation of the intramedullary reamer, it should only be connected with the motor switched off and the system safety lock activated. Failure to do this can lead to damage to the drill and to injuries.

### Please note

When operating the motor drive unit, be sure to follow the instructions carefully.

### Caution

In order to avoid a high thermal load bursts of forward movement and overloading the motor drive system, use only sharpened intramedullary reamers that are free of defects.

### Please note

In order to prevent the flexible drill shank 2 from warping, avoid kinking the intramedullary reamer during use or while cleaning. Damaged intramedullary reamers should be set aside and not used.

## 4.2 For the patient

### Caution

In order to achieve optimal results and avoid thermal damage to bones and tissues (necrosis), drilling should be performed using constant forward pressure.

### Caution

Working with sharp-edged tools can give rise to tears or perforations in surgical gloves. This can in turn give rise to contamination and infection.

Therefore, avoid touching the cutting edges of tools when using or changing them.

## 4.3 For the unit

### Caution

In order to operate the unit safely, and in the interest of preventing injuries, only use intramedullary reamers whose cutting edges 1 and flexible drill shanks 2 show no sign of damage.

### Caution

Only use the intramedullary reamer if its functions have been tested as described in (see section 7) and if no damage or defects are found.

### Caution

The intramedullary reamer should only be sterilized with steam.

### Please note

Sterilization should be carried out via an approved sterilization procedure. (see section 9.2)

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### 5. Putting into operation

Attachment configurations that are not specified in the instructions for use may only be used if they have no negative impact on the performance and safety parameters of the intended applications.

In order to operate the intramedullary reamer, a compatible motor drive is needed. The motor drive must have sufficient torque (>700 Nm), a compatible number of rpm's (150-300 rpm), as well as the correct shank adapter (DIN 58809, Harris, Trinkle, Hudson or AO).

The intramedullary reamer can be used in conjunction with other systems, providing compatible adapters are used.

### 6. Preperation

Only use the intramedullary reamer if the cutting edge of it's drill head 1 and the shank 2 show no signs of damage. Connect the intramedullary reamer with a suitable shank profile (DIN 58809, Harris, Trikle, Hudson or AO) to the adapter of the respective motor drive.

Follow the instructions that accompany the respective handpiece.

### Warning

Both injuries and irreparable damage to the drill can result if it is operated in a counter-clockwise (lefthand) direction. The intramedullary reamer should only be operated in a clockwise (righthand) direction.

### Caution

The intramedullary reamer is delivered unsterilized. It must therefore also be sterilized prior to initial use (see section 9).

### Caution

In order to avoid accidental operation of the intramedullary reamer, it should only be connected with the motor switched off and the system safety lock activated. Failure to do so can lead to damage to the drill and to injuries.

### Please note

When operating the motor drive unit, be sure to follow the instructions carefully.

### 7. Functional test

Before each use, both the motor drive and intramedullary reamer that is to be used should be inspected. Be sure that neither flexible drill shank 2 nor the cutting edges are damaged.

Ensure that the intramedullary reamer is seated securely in the motor drive adapter. When doing this, hold the motor drive firmly in one hand and pull in a forward direction on the intramedullary reamer with the other. If the intramedullary reamer is firmly seated, it will remain in the in the handpiece adapter when you pull on it.

Ensure that the guide spindle and intramedullary reamer configuration to be used for drilling is a correct one. At the same time, push the guide spin-through the longitudinal boring of the intramedullary reamer. The guide spindle should move smoothly in the boring. In order to avoid hazards arising from wearing away spindle material during use, watch out for crimped or abraded guide spindles, and set them aside.

### Warning

The use of either a guide spindle that is excessively curved or warped, or a crimped intramedullary reamer (or both) can lead to increased friction and thereby to unintended removal of material and to binding of the drill.

Only guide spindles and intramedullary reamers should be used whose surfaces are not damaged and whose shanks are free of defects and are not warped.

### Caution

Working with sharp-edged tools can give rise to tears or perforations in surgical gloves. This can in turn give rise to contamination and infection.

Therefore, avoid touching the cutting edge of tools when using or changing them.

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### Caution

In order to operate the unit safely and in the interest of preventing injuries, only use intramedullary reamers whose cutting edges 1 and flexible shanks 2 are free of defects.

### Caution

Only use the intramedullary reamer if its functions have been tested as described in (see section 7) and if no damage or defects are found.

## 8. Operation

The intramedullary reamer should only be used in conjunction with a compatible guide spindle. The choice of guide spindle is determined by the diameter of the guide of the intramedullary reamer. The guide spindle is first used to align the section of bone on the correct axis, and should be guided only with the hand, which should be positioned on the special handle. The drill is guided by means of the inserted guide spindle. Begin the smallest diameter appropriate to the diagnostic procedure and increase by increments of 0.5-1.0 mm until the desired end diameter is achieved.

For information pertaining to operation of the motor drive, please refer to the motor drive instruction manual.

### Warning

The use of either a guide spindle that is excessively curved or warped, or a crimped intramedullary reamer (or both) can lead to increased friction and thereby to unintended removal of material and to binding of the drill.

Only guide spindles and intramedullary reamers should be used whose surfaces are undamaged and free of defects and whose shanks are not warped.

### Warning

Injuries, as well as irreparable damage to the drill can result if it is operated in a counter-clockwise (left-hand) direction. The intramedullary reamer should only be operated in a clockwise (right-hand) direction.

### Caution

In order to achieve optimal results and avoid thermal damage to bones and tissues (necrosis), drilling should be performed using constant forward pressure.

### Caution

In order to avoid a high thermal load bursts of forward movement and overloading the motor drive system, use only sharpened intramedullary reamers that are free of defects.

### Please note

In order to prevent the flexible drill shank 2 from warping, avoid kinking the intramedullary reamer during operation or cleaning. Damaged intramedullary reamers should be set aside and not used!

## 9. Cleaning, disinfection, sterilization

Minimum criteria for cleaning and disinfecting solutions: These are to be determined by national government regulations.

### 9.1 Cleaning / disinfection

Following use, immerse the intramedullary reamer in an active cleaning disinfection solution. The manufacturer's instructions with regard to dilution ratios, action time, etc. must be observed.

Then clean the intramedullary reamer inside and out by holding it under running water. While doing this, bend the flexible drill shank 2 slightly in order to remove any encrusted material, using, if necessary, a soft brush. To clean the inside, a guide spindle or narrow round brush can also be used.

Final cleaning of the flexible drill shank 2 should be carried out by gently and carefully bending and twisting it while exposing it to ultrasonic.

Finally, rinse and the intramedullary reamer thoroughly, and then dry it.

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When cleaning the guide spindle, watch out for surfaces that are damaged, i.e. that are excessively scratched, abraded, or worn. Damaged guide spindles should be set aside and not used.

During preparations for each use, the intramedullary reamer should be inspected for damage to its cutting edges 1 and on the flexible drill shank 2. Damaged intramedullary reamers should be set aside and not used.

### Caution

Working with sharp-edged tools can give rise to tears or perforations in surgical gloves. This can in turn give rise to contamination and infection. Therefore, avoid touching the cutting edge of tools when using or changing them.

### Please note

In order to prevent the flexible drill shank from warping, avoid excessive bending of the intramedullary reamer during operation or cleaning. Damaged intramedullary reamers should be set aside and not used.

## 9.2 Sterilization

Sterilization should be carried out by a validated steam sterilization method (e.g. sterilizer according to EN 285 and and validated according to EN 554).

### Autoclave:

Steam autoclave, Temperature = 121° to 123° celsius, pressure 1 – 1,2 bar (15-17 psi), at least 30 minutes in packed condition. At temperature of 131° up to 135° celsius, 1 - 1,2 bar (15-17 psi) the pressure is reduced to approx. 20 minutes.

### Autoclave:

Autoclave with backing pressure : during the backing pressure cycle the air is evacuated from the chamber before steam is let in. Standard sterilization time for packed instruments, 135°celsius at 2-3 bar (27-30psi) minimum 4 to 10 minutes.

### Caution

The intramedullary reamer should only be steam sterilized!

## 10. Troubleshooting list

Fault	Cause	Fault detection	Rectification
The intramedullary reamer doesn't turn	The motor drive is not attached	The motor drive fails to Engage the reamer	The motor drive is not correctly attached
	The motor drive is malfunctioning	The motor drive fails to turn	Consult motor drive instructions for use
Instrument fails to cut properly	Bone material in the flutes or drilling canal	Bursts of forward Movement, overheating	Take the intramedullary reamer out of the motor drive and remove bone material
	Dull cutting edge		Replace intramedullary reamer; service have to be by origin manufacturer
Intramedullary reamer fails to achieve desired socket depth	Warped guide spindle or Intramedullary reamer	Intramedullary reamer is Difficult to center with the Guide spindle or cannot be Cenered at all	Replace guide spindle and intramedullary reamer

For further information regarding technical problems, please consult the appropriate instructions for use.

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### 11. Technical service

#### Maintenance / repairs

Sharpening of the intramedullary reamer should only be carried out by origin MANUFACTURER.

Contact MANUFACTURER technical service department even if only minor technical problems arise. In so doing, more problems or breakdown of the intramedullary reamer will be prevented from occurring. Replace any dull or damaged intramedullary reamers.

For information pertaining to maintenance of the motor drive, please consult the instruction manual. The MANUFACTURER shall be held responsible for the safety, reliability and performance of this product only

- if any installation, additions, adjustments, service, repairs or changes with regard to this product are carried out solely by the manufacturer
- and if the product is used in accordance with the instructions accompanying it

Only original MANUFACTURER replacement parts might be used for repairs. The user must obtain from the company that has carried out any repairs a document specifying the type and extent of the work performed; this document should bear the company stamp, date and authorized signature.

### 12. Technical data

Intramedullary reamer diameter	Ø 6.0 mm up to Ø 18 mm
Motor drive rpm	150 – 300 rpm with max. torque for reamer shaft = 10 Nm
Compatible shank adapters	DIN 58809, Harris, Trinkle, Hudson, AO – Synthes

### 13. Accessories

The compatible handles and guide spindles for drilling with intramedullary reamers are:  
Guide spindles with round head (olive), made of implant material DIN ISO 5832-1

Guide spindle diameter	2.0 mm for intramedullary reamer: Ø 6.0 mm up to 7.5 mm
Guide spindle diameter	3.0 mm for intramedullary reamer: Ø 8.0 mm up to 18 mm

Guide spindle length:	900 mm
RECOMMENDED HANDLE :	JAKOBS CHUCK WITH T - HANDLE

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