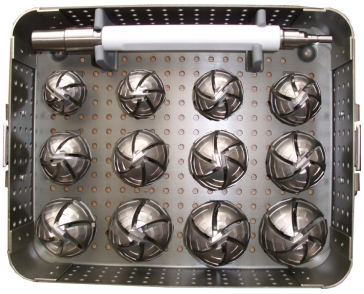
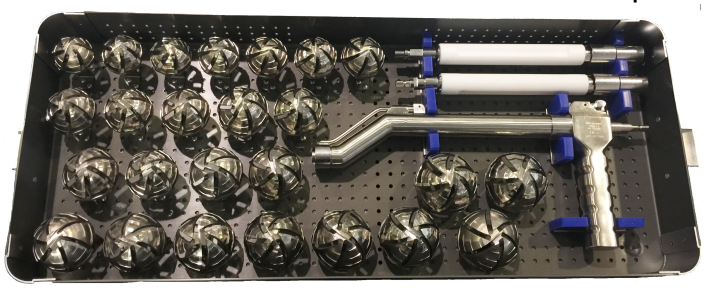
EPM Mueller® LTC. Reamer

ST, MI2 and Mini

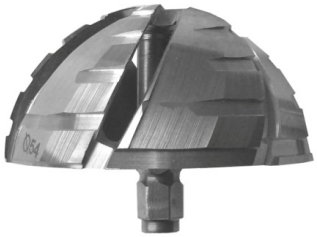
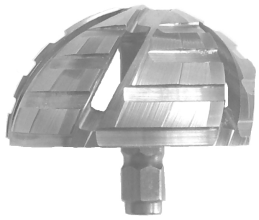
FDA Establishment Registration Number: 3003803087

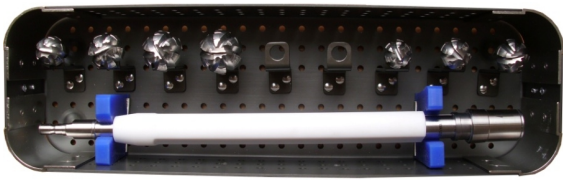


EPM MUELLER® Reamer LTC.ST.12+ 2 ST Adapter in Korb



EPM MUELLER® Reamer LTC.ST.25+ 2 ST und 1 Offset Adapter in Box

LTC.ST   LTC.MI2



LTC Mini

EPM Endo Plant Müller GmbH

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Technical documentation

Content: EPM Müller ® reamer

The EPM MUELLER® *Reamer*

Recent studies (2009) shows that liner deformation caused by interference impaction contributed to a 2%-10% difference in the locking mechanism retention strength in the designs studied, as well as, increased asymmetric contact damage. (6*)is a new generation Acetabular Reamer offering unique standards of precision and accuracy.

Current acetabular reamers of the traditional 'cheese grater' design with circular cutting edge holes have the disadvantage that the blades do not provide a consistent surface to the radius of the reamed space. In addition the natural tendency to lateral movement creates an asymmetrical cut, resulting in an uneven and irregular interface between cup and tissue.

Using the same principle as an airplane propeller, the angle of the blades alters as they reach the apex guaranteeing a uniform slice, and a significantly more precise reaming action.

The shape of the blades ensures they maintain maximum cutting, while the rotating spiral action also ensures the blades remain free of chips. This therefore minimizes the pressure required, with subsequent minimalizing of Thermo-Osteonecrosis. As a result of extensive testing, further design modifications of the cutting edges significantly reduced vibration and 'chatter'.

The EPM Mueller Reamer is self-centering and produces extremely low vibration levels.

The production methods used in Reamer manufacture are used in the aerospace industry, with the latest 5-axes CNC bow technologies providing the highest standards of accuracy.

A newly developed ergonomic quick-connector for the Reamer further enhances ease of use. Currently available with a AO, Stryker extension, it can be adapted to all systems.

The narrow diameter improves visibility for the surgeon and is quick and simple to use and has been well received by surgeons in evaluation.

Achieving stability is a prerequisite for allowing bone to grow into the porous surface of non-cemented acetabular cups used in total hip replacement.

Studies have shown that relative interfacial micromotion, the parameter used to study stability, is influenced by the discrepancy between cup and bone and the subsequent amount of interface (5*).

The highest stability was shown where the discrepancy was 0.25 mm. More or less led to instability and also the potential for wear particles between cup and bone (4*, 5*).

This study suggest that all modular acetabular components are not alike and that care should be taken when employing thin metallic shells. (6*)

Further, clinical considerations suggest that pelvic under-reaming where thin shells are employed may be contributory to early damage/disassociation of modular, acetabular components.(6*)

Conclusion:

an accurate calibration of Acetabular reamer process is desired for a stabile cup. (4*)

1* -E.W. Morscher. – Endo Prothetic 1995

2*-DeLee, J.G.,Charnley, J., 1976 –Radiological demonstration of cemented socket in hip replacement. Clin. Orthop.

3*-Goodmann,S.B., Charter, D.R.,1987-Acetabular lucent lines and mechanical stress in total hip altroplasty. J.Arthroplasty 2.

4*-Jain R.Spears,Michael M. Morlock,Erich Schneider und Ekkerhard Hille-Internal Projects 1999-2002

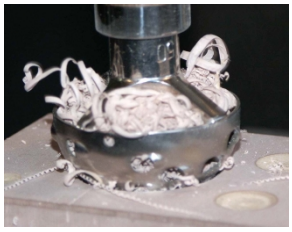
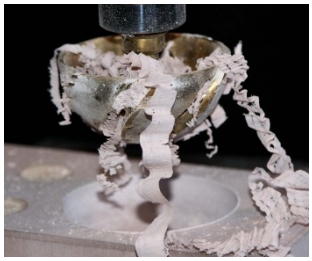
Relative micromotion at the bone-implant interface during the gait-cycle: A finite element approach

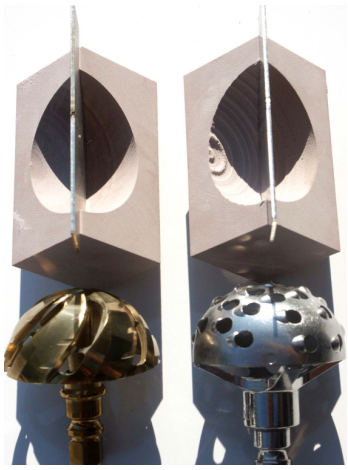
5*- Spers, I., Morlock, M., Pfleiderer, M., Schneider, E.,und Hille, E. –Internal Projects 1999-2002. The influence of friction and interference on the seating of a press-fit cup: A finite element investigation

6*-Paul D. Postak, BSc; Mircea Rosca, MSME; A Seth Greenwald, DPhil Oxon,-Cleveland Ohio. 2009. Thin Acetabular Shells Increase the Disassociation Risc of Modular Liners.

Performance Testing

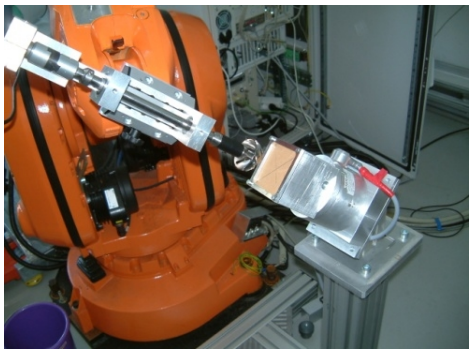
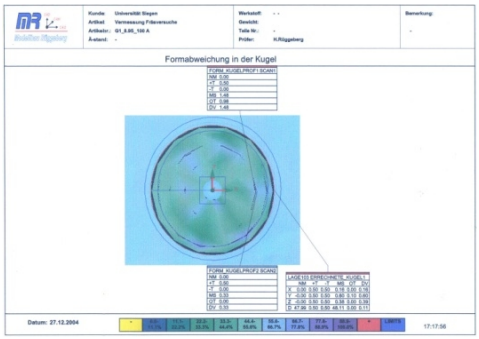
First EPM Mueller Reamer geometries were tested 2002 at a CNC facility with consistent reproducible tests on both wood and epoxy.



Analysis of the reamed space with precision instruments shows a clear difference in the quality and precision of the surfaces between traditional reamers and the EPM Mueller Reamer.

Sphericity test with the EPM Mueller reamer, dec. 2004

The test shows a rage of 0.15mm between the lowest and the highest measured radius

Torque test EPM Mueller reamer, old and new geometry, versus usual reamer,

Active Implants (Israel) Ltd. http://www.activeimplants.com

Precision reamers torque test

1. General :

Erich Muller sphere reamers producing very high torque during surgery the torque is so high that the doctors are afraid to break the Pelvis.

In order to make new reamers that would reduce this high torque two suggestions were made the first is a reamer with maximum chip depth of 0.2 mm (compare to the high torque reamer with 0.8mm depth.) and the second one is a sharper free angle with a 0.4 chip depth, this report is describing the comparative test and test results of the new reamers in comprise to the old reamers and to Precimed cheese grater geometry reamer.

The results are not in absolute values.

2. The test tools and materials:

2.1 Torque drill with values between 1 to 16.
2.2 Sawbone block 20 (cancelous bone).
2.3 Sawbone block 80 (cortex bone).
2.4 Sawbone grip tool.
2.5 Precimed cheese grater reamer diameter 44.
2.6 Erich reamer diameter 44 with 0.2 chip depth.
2.7 Erich reamer diameter 44 with 0.4 chip depth and modified free angle.
2.8 Erich reamer diameter 48 with 0.8 chip depth no chip breaker geometry.

3. The test description:

reaming in sawbone is known to produce large torque similar to the torque in bones, during our ream test we notice that there is very good correlation between the torques in bone and in sawbone.

3.1 Each of every reamer from above was tested in the torque drill against sawbones 80 diameter 44 predrilled spheres with press force of approximate 250N.

פקס: 09-8659221 טלפון: 09-8659220 אקטיב אימפלנטס ישראל המלאכה 43 ת.ד. 8395 נתניה 42505
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Active Implants (Israel) Ltd. http://www.activeimplants.com

3.2 Each of every reamer from above was tested in the torque drill against sawbones 20 diameter 44 predrilled spheres with press force of approximate 250N.
3.3 Reamer 48 was tested in the torque drill against sawbones 80 diameter 48 predrilled spheres with press force of approximate 250N.
3.4 Reamer 48 was tested in the torque drill against sawbones 20 diameter 48 predrilled spheres with press force of approximate 250N.
3.5 All the reamers were tested by two different people who didn't know what in the drill and gave their impression about the torque they felt during reaming.

4. Results:

4.1 Table 1- relative values test.

	Sawbone 20 torque	Sawbone 80 torque
Erich Reamer 44 chip depth 0.2	6	14
Erich Reamer 44 chip depth 0.4 sharp free angle	6	10-12
Erich Reamer 48 chip depth 0.8 regular(old)	12-14	Out of scale (greater than 16)
Precimed cheese grater reamer 44	8	14-16

4.2 Impression test: Both people thought that the lowest torque was produced by the Erich reamer 44 chip 0.4 modified sharp free angle.
4.3 Impression test: The second low torque impression was the Precimed cheese grater reamer 44 and very similar to the Erich Reamer 44 chip depth 0.2.

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4.4 Impression test: Both people impression was that the Erich Reamer 48 chip depth 0.8 regular(old) was producing the largest torque.
4.5 Visual inspection showed that the roughness of the surfaces that was achieved by the Erich Reamer 44 chip depth 0.2 and 0.4 free angle were similar the 0.8 was best and the Precimed was the worst, when surfaces of the Erich Reamer 44 chip depth 0.2 and 0.4 free angle were reamed under low pressure at the end of the reaming process for 4 revolutions and the roughness was similar to the 0.8 old reamer.
4.6 Sphericity and diameter were not tested

5. conclusions:

5.1 Erich Reamer 44 chip depth 0.4 modified sharp free angle is producing very low torque even compare to a regular cheese grater reamer.
5.2 The surface roughness that the new reamers are producing is acceptable and using 4 low pressure revolutions can achieve the same roughness as the old reamers.

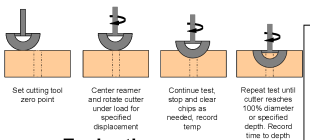
EPM Mueller Acetabular Reamer comparison tests, versus other reamers

2007

Paragon Medical Test Procedure PMTP-003
Test Title
Acetabular Reamer Cutting Endurance Test
Objective
To determine the endurance of the cutting surfaces of an Acetabular reamer

Global Design Center (GDC)

Test Summary



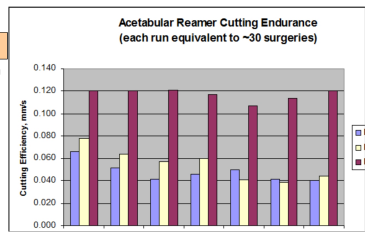
Fully Machined Acetabular Reamer Performance Evaluation

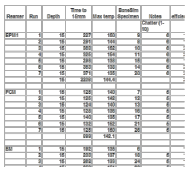
Summary

A new design of an acetabular reamer is being evaluated for cutting endurance, efficiency, and profile. This newly designed reamer is a highly ridged reusable device machined from 17-4 stainless steel and surface ground cutting edges.

Acetabular Reamer Comparison

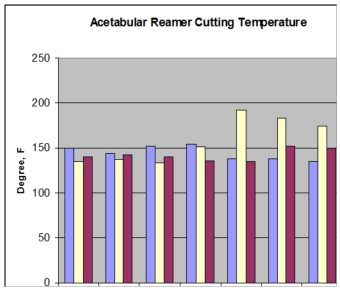
Results

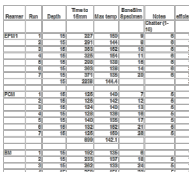




Acetabular Reamer Comparison

Results

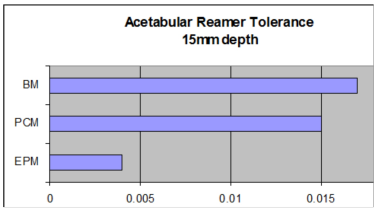


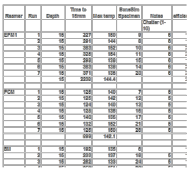


Acetabular Reamer Comparison

Results

Profile





Clinical Evaluations

Since July 2003 the EPM Mueller® Reamer has been in clinical test use at several university clinics. The responses and opinions of the evaluating surgeons are extremely positive.

EPM Mueller® Reamers provides

-easy action
-precise axial correction
-exact and accurate depth control
-smooth and precise chip-free reaming

The primary stability of the implanted cups has been very good.

Subsequent x-rays showed accurate alignment.

(SOTI clinic Budapest)

KLINIKUM GARMISCH-PARTENKIRCHEN GmbH

82467 Garmisch-Partenkirchen, Auenstraße 6
Lehrkrankenhaus der LMU München www.klinikum-gap.de

Evaluation of new reamers To whom it may concerns Unseren Zeichen: CSF/30.05.2009

We have tested the new reamer set provided to us by Endoplant in approximately 180 hip replacement surgeries so far.
We found that the reamers were easy to handle and produced a precise reaming result. The reamed bony surface was much smoother than with conventional reamers and we could ream an exact hemisphere. Whereas other reamers tended to stray from the intended course the new set stayed true.

Reaming should be attempted carefully, since the reamers are sharp and if too much pressure is applied could make them catch. This is not a problem if anticipated and we have not encountered a dangerous situation so far.

Cutting can be achieved centrally and on the sides, so that a lateral reaming motion can be attained if desired, especially if parts of the acetabulum are harder than others.

We attempt an exact fit or interference fit for our hemispherical acetabular implants and the new reamers provide us with a very dependable reamed cavity.

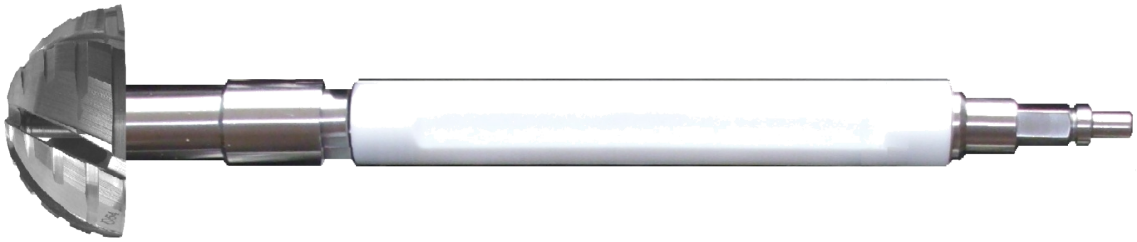
The reamers are in everyday use in our department.

Dr. Christian S. Fulghum endogap – center for joint replacement surgery

1. **EPM MUELLER® LTC.ST. and Mini Reamer hemisferical with adaptor ST.V7**

4.1 Components:

1 4 (5) (6) 3 2 2a



EPM MUELLER® Reamer LTC.ST with adaptor ST.V7 Fig.4

1. EPM MUELLER® Reamer LTC.ST. or Mini
2. shaft with AO hand or powertool connection at one end and a 6 cant bed for the reamer at the other end, covered from the cover (4)
3. handel
4. cover
5. stop-fork
6. spring

4.2 Handling

Reamer insert

Pull the cover sleeve.
Add the reamer shaft completely in the 6 square bed in the head of the shaft.
Release the cover sleeve, the spring moves the cover forward and the reamer is fixed by the stop fork.
Caution: Check if the reamer is firmly seated in the shaft, by trying to pull it out.
It should sit stable in the 6 Kant bed stable.

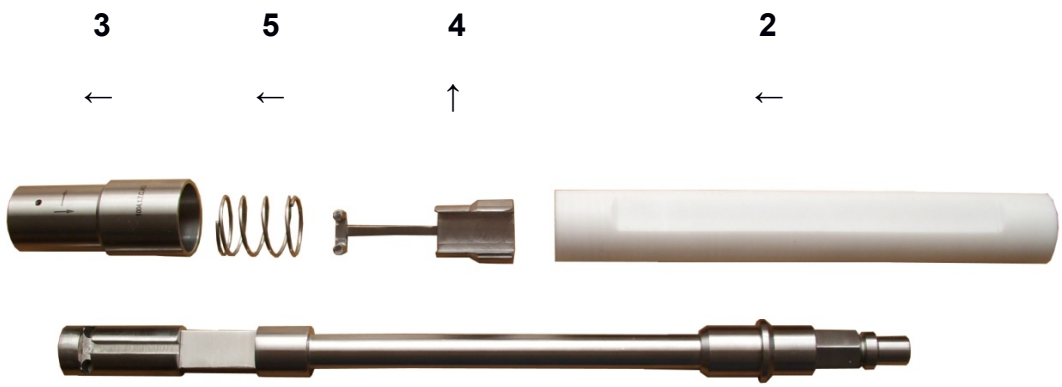
Reaming

Use no more rotation than 80-90 revolutions per minute.
At the beginning, exert a lower pressure and increase it during the reaming process.
The reamer is self centering but if necessary the surgeon can change the penetrations axis.
If you have reached the desired size of the cavity, make 2-3 reaming-turns without pressure to achieve a smooth surface of the cavity.

4.3 Cleaning and sterilization, removal instructions

Remove the reamer as shown in Insert.
Pull the cover sleeve, down by half, turn it to the right and then slide it off the shaft.
Caution: hold always the cover sleeve because of the spring under the cover.
Remove the spring from the shaft.
Remove the stop fork from the shaft.

Pull PTFE handle off the shaft.
Reverse order for Assembly



1 Abb.5

5. EPM Mueller® LTC.MI2 Reamer with offset adaptor MIS. V5

5.1 Components:

1 (8) 2 (7a) 3a (2b) 2a (2c) (8) 3 4 (7) 5 6 6a (8) 7b

Abb.6

1-Reamer LTC.MI2

2 shaft cover sleeve with arm button (2a), arm, arm spring (2B) and fastening screw (2c)
3 waves top coat with cover sleeve arm housing (3a)
4 shaft base coat
5 handle
6-handle stopper with sliding Blocker(6a)
7 double-waves (7) with reamer 6-Kant bed with 3 ball stopper (7a) and AO or S power tool connection (7B)
8-PEEK bearings

5.2 Handling

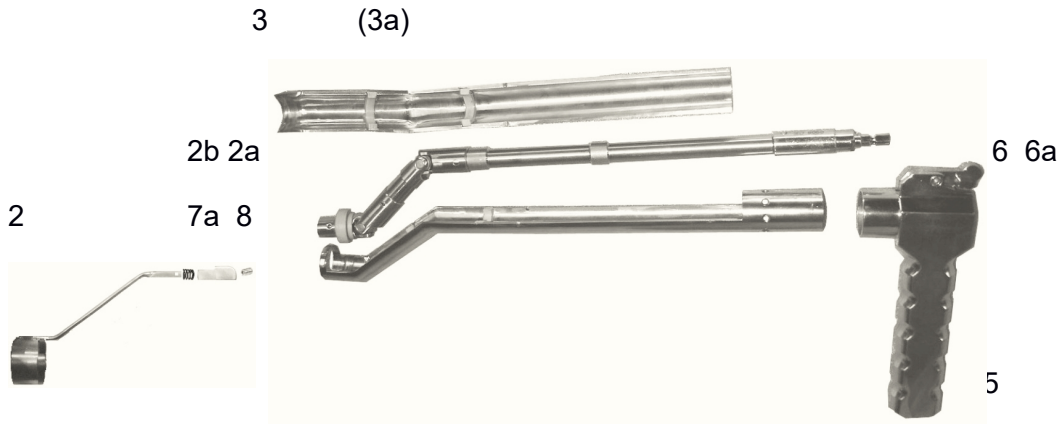
Reamer insert

Push the sleeve-arm button (3a) forward until stops to move the cover sleeve (2) and hold it firmly.
Insert the reamer in the 6-Kant (7a) bed in the double-wave.
Release the button and the spring will bring the cover sleeve again in the close position.
Caution: Check if the reamer is firmly seated in the shaft, by trying to pull it out.
It should sit stable in the 6 Kant bed.
Pull back the slide blocker (6a), press the stopper (6) handle and turn the handle (5) to the desired angle, release the stopper and further turn the handle until the stopper snaps in one of the shaft base coat (4) holes, then push the blocker to front to fasten the stopper.
Caution: Try whether the handle is securely fastened.
Place the power tool on the AO link (7B). You can use also Stryker connection, which are fixed at the end of the double wave.

Reaming

Use no more rotation than 80-90 revolutions per minute.
At the beginning, exert a lower pressure and increase it during the reaming process.
The reamer is self centering but if necessary the surgeon can change the penetrations axis.
If you have reached the desired size of the cavity, make 2-3 reaming-turns without pressure to achieve a smooth surface of the cavity.

5.3. Cleaning and sterilization, removal instructions



Remove the reamer as shown in Insert. With the Allen key 2.5, remove the fastening screw (2 c) by holding the cover in front and the bottom all the time, pull the arm bottom (2B), then the spring (2 c), and then the cover sleeve (2) to the front.
Pull the slide blocker (6a) and then the handle stopper (6) and remove the handle (5) from the waves-coat (3, 4).
Raise the Wave top coat(3) until the shaft PEEK bearings release the coat bearings bets than pull the coat backwards to unhook it from the front.
Take the double-shaft (7) in the middle and lift it until the shaft bearings release the coat bearings bets (4) hack out and then pull it back until the front part of the wave leave the front casing ring of the bottom coat and then push forward to remove it from the back casing ring.
You can`t dismantle the double-shaft into individual parts. By removing the screw on the handle with the Allan key 2.5 you can remove the handle stopper and the slide Blocker.

6. CLEANING and STERILIZATION

6.1 Preparation

Brand new instruments and those returned from repair must be removed from their transportation packaging before storing and / or inclusion in the instrument usage and processing cycle.

6.2 Storage

Store it at room temperature in dry rooms. Condensate may cause subsequent corrosion damage.
Never store it near chemicals such as active chlorine which emit corrosive vapors.
To avoid mechanical damage during processing, store it from the beginning in suitable racks or retainers.
Before using, they must be sent through the entire processing cycle in the same manner as used instruments.

The reprocessing comprises:

- Preparation (pretreatment, collecting, precleaning and taking the instrument apart.
- Cleaning, disinfecting, rinsing, drying
- Visual inspection of clearness and acceptable condition of material
- Care and repair where required
- Functional test
- Marking
- Packaging and sterilization, approval for reuse and storage

Validated cleaning, disinfecting and sterilization processes, supplemented by defined configurations for loading the washers/disinfectors and sterilizers are an indispensable prerequisite for quality assurance.
Automated reprocessing with thermal disinfection and steam sterilization should be preferred.
Use correct water quality!
When using softened water, especially when applying thermal disinfection in the final rinse, anodized aluminium surfaces might be subject to attack due to an increased pH value.
Using demineralised water for steam sterilissation, limit values for feed water quality conforming to EN 285 and ISO 17665 are required.
We recommend using demineralized water for the final rinse for the following reasons:

- No spoting
- No increase in concentration of corrosive constituents, e.g. chlorides
- No dried crystalline residues which could have a negative effect on the downstream sterilization process
- Protection and stabilization of anodized aluminium surfaces

6.3 Returned instruments

Only if the instruments have been cleaned, disinfected, dried and have been declarated hygienically safe

6.4 Cleaning and Disinfecting

Any residues should be removed.
Never immerse stainless steel instruments in a physiological salt (NaCl) solution, it leads to pitting and stress corrosion cracking.
The passive layer of brand new instruments is necessarily still thin and so these instruments tend to critical treatment conditions than are older used instruments.

Avoid long intervals between use and treatment for reuse.
For manual cleaning, active non-protein-fixing cleaners with or withaut antimicrobial effect and/or enzymes are to be used.
Regarding detergents and desinfectants, the manufacturer`s instruction concerning concentration, temperature and exposure time should always be strictly followed!
Use soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning.
To prevent water spots (spotting), a final rinse using fully demineralised water is recommended. After this the instrument must be dried carefully immediately.
By machine-based cleaning, only validated machine cleaning and desinfecting processes (DIN EN ISO 156883 and national guidelines) should be used.

6.5 Check and care

Instruments must be checked visually – tactile and be macroscopically clean.
Maintance means targeted application of a lubricant milk to the joints, threads or friction surfaces of instruments. This prevents metal on metal friction and therefore constitutes a preventive measure against friction corrosion.
Requirements for care agents:

- Paraffin/white oil based, in accordance with the current European or United States Pharmacopeia
- Biocompatible
- Suitable for steam sterilization and vapor permeable

Instruments must not be treated with care agents containing silicone oil.
The proper functioning of the instruments must be assured by testing.
Apply instrument oil to tube, rod and screws periodically to minimize wear friction.
The new instrument: has to be cleaned up and disinfected before sterilisation.

6.6 Packaging

International standard EN ISO 11607 1 and 2 apply to packed items requiring sterilization.
It must be possible to mark and identify the package with information such as:

- Sterilisation date
- Packer
- Expiry or “use before” date (if date has been defined)
- Contents

6.7 Sterilisation

It is important to use only sterilisation methods and sterilizers that allow validated sterilization processes conform national guidelines.
Sterilisation accessories and packaging materials must be selected in accordance with the items to be sterilised as well as with the sterilisation method used.
Steam sterilization is the method of choice and is performed with saturated steam, usually at 134°C.
Use validated steam sterilization processes in accordance with ISO 17665, EN 554 (or DIN 58946 Part 6 in Germany)

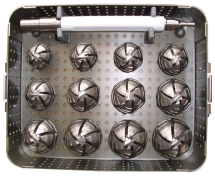
6.8 Sterile storing

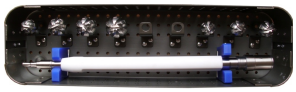
To guarantee the sterility of instruments until they are used on the patient, germ-tight packaging is absolutely essential.
Further requirements for the protected storage of sterile supplies and the prevention of corrosion damage include a dust-free and dry environment and the prevention of temperature fluctuations.

7. Technical data

7.1 EPM Mueller® LTC.ST.12 acetabular Reamer Set 1007.1.12A.LTC.ST

· Reamer size ST: Æ 44mm – 64 mm (12 pieces-Set.)
· Reamer Adaptor V7.ST with AO or Stryker Powertool link
· Anodisied Alubox with Lid, Reamer supports and Silicon Adaptor supports (40/25/7)



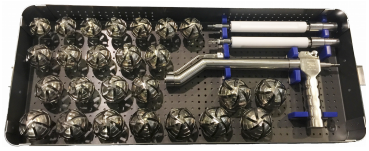


7.2 EPM Mueller® LTC Mini Reamer 1007.1.XLTC.Mini

. Reamer size Mini: Æ 18 mm- 32 mm
· Reamer Adaptor V7.ST with AO or Stryker Powertool link
· Anodisied Alubox with Lid, Reamer supports and Silicon Adaptor supports (45/12/7)

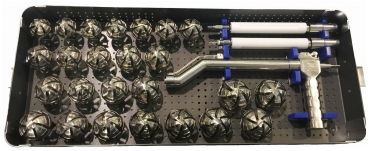
7.3 EPM Mueller® LTC.ST.25 acetabular Reamer set 1007.1.25LTC.ST.-2ST-O

· Reamer size ST: Æ 40mm – 64 mm (25 pieces-Set.)
· offset Reamer Adaptor MIS.V5 with AO or Stryker Powertool link
. 2x Reamer Adaptor ST.V7 with AO or Stryker
· Anodisied Alubox with Lid, Reamer supports and Silicon Adaptor supports (54/25/7)



7.4 EPM Mueller® LTC.MI2.25 acetabular Reamer set 1007.1.25LTC.MI2.-2ST-O

· Reamer size MI2: Æ 40mm – 64 mm (25 pieces-Set.)
· offset Reamer Adaptor MIS.V5 with AO or Stryker Powertool link
. 2x Reamer Adaptor ST.V7 with AO or Stryker
· Anodisied Alubox with Lid, Reamer supports and Silicon Adaptor supports (54/25/7)



8. Supply/ Spare parts

1003.1.44LTC.ST to 1003.1. 64LTC.ST Reamer LTC.ST from 44mm to 64mm

1003.1.18LTC.Mini to 1003.1.32LTC.Mini Reamer LTC.Mini from 18mm to 32mm

1007.1.12A.LTC.ST.AO(S) 12 Reamers ST+Adaptor ST.AO(S)+Box

1007.1.X.LTC.Mini X Reamers Mini+Adaptor ST.AO(S)+Box

1007.1.25AB.LTC.ST.-2ST-O(AO(S)) 25 Reamers ST+2 ST+1 Offset Adaptor.(AO or Stryker)+Box

1007.1.25AB.LTC.MI2.-2ST-O(AO(S)) 25 Reamers ST+2 ST+1 Offset Adaptor.(AO or Stryker)+Box

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