For USA only

Application and safety instructions for the MEISINGER **EN**

Micro Screw System
Micro Screw System Basic

Screw System for safe Stabilization of Cortical Bone Graft Transplants ‘Olsberger Konzept’ by Prof. Dr. Fouad Khoury

85FLBM25USA -0222

Art.-No.: BMS00, BMSBA

Device Description

The Micro Screw System and Micro Screw System Basic are used for the safe fixation and stabilization of cortical bone grafts. These systems contain osteosynthesis screws made of surgical stainless steel with diameters of 1.0 mm and 1.2 mm.

Indications for Use

The Micro Screw System and Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field.
Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function, such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.

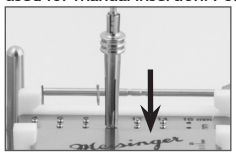
Surgical recommendations Micro Screw System / Micro Screw System Basic

Placement of the pilot hole through bone cylinder and recipient bone
For the application of the Micro Screws, a pilot hole through bone graft and recipient bone is necessary. This is done using a twist drill with a 0.2 mm smaller diameter:

- 1.0 mm Micro Screw ≙ twist drill MSPB1 or initial bur 202RF 008 (Ø 0.8 mm)
- 1.2 mm Micro Screw ≙ twist drill MSPB2 or initial bur 202RF 010 (Ø 1.0 mm)

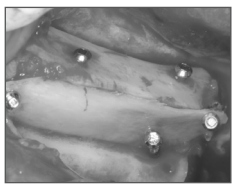
The respective drilling should take place intermittently and under constant cooling with sterile, physiological saline solution. Since the Micro Screws have a self-tapping thread due to specially shaped thread flanks, no expansion drilling (gliding hole) to the outer diameter of the screws is necessary.

Selection of the screwdriver and picking up of the Micro Screws
Depending on the selected procedure (machine or manual screw insertion), the appropriate screwdriver must be selected. The screwdrivers MSSDE (screwdriver basic) or MSSDM (optionally with claw MSGSD) are used for manual insertion. For machine insertion with the angle piece, the MSSDW, screwdriver RA, is used.



NOTE: The screwdriver with claw has a special gripping device. As soon as the connection between screwdriver and Micro Screw is given over the square, this gripping device is closed by pushing the sleeve in the direction of the Micro Screw. The gripping device thus encloses the screw head of the Micro Screw to be picked up, which ensures a reliable hold and thus enables a secure transfer to the operation area and safe application.

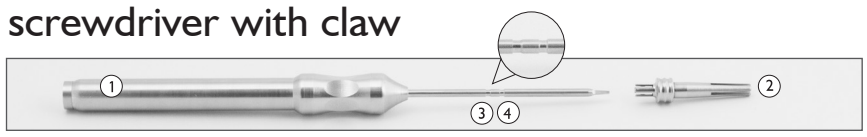
Fixation of the bone graft



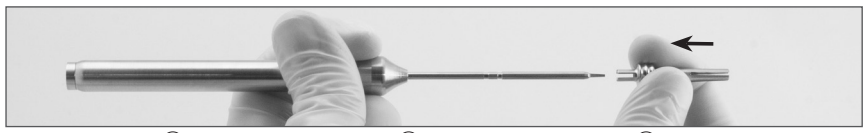
Using the selected screwdriver, a Micro Screw of appropriate length is picked up and the bone graft is attached to the recipient bone. The Micro Screw can be inserted into the bone without thread cutting, as it has a self-tapping thread design. The Micro Screw is tightened in a controlled manner until the bone cylinder is firmly fixed in the site. The bone must not be over stressed. In addition, during the insertion process, the axis specified by the pilot hole must be observed to prevent the screw from tilting. If a safe fixation of the graft with one screw is not possible, fixation with at least 2 screws is recommended to prevent any rotation.

Removing the Micro Screws
The Micro Screws are to be removed counterclockwise using a screwdriver from the Micro Screw System.

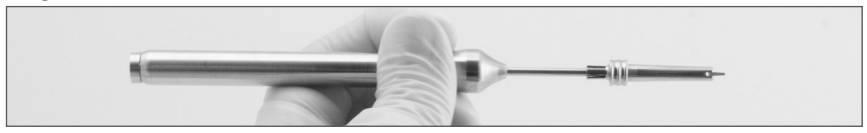
Instructions for disassembly and assembly of the screwdriver with claw



Screwdriver ①, Claw ②, Groove 1 ③, Groove 2 ④



1. Attach the claw ② to the screwdriver blade ①, as shown. Push the claw ② until it snaps into groove 1 (③, open position).



2. Now the screwdriver with claw is ready to use. To secure a screw, push the claw ② in the direction of the screwdriver blade over the screw until it snaps into groove 2 (④, closed position). For Disassembly push and remove the claw ② into the direction of the screwdriver blade.

Contraindications
Basically, general medical as well as local, absolute, and relative contraindications for dental surgical procedures must be considered.

Absolute contraindications
- Active infections in or near the area to be augmented as well as local or systemic pathological processes (e.g. symptoms such as fever, local inflammation, abscesses)
- Insufficient bone volume (quality / quantity)
- Diseases or medication that impair bone metabolism

Relative contraindications
- Dentoalveolar growth which has not come to an end (exception: cases in which no dentoalveolar growth can be expected, e.g. ectodermal dysplasia)
- Known allergies and/or foreign body reaction to the alloy composition of the Micro Screws
- Systemic and/or metabolic diseases or medical treatments that lead to progressive deterioration of the bone (e.g. cortisone, immunosuppressants, bisphosphonates, diabetes, etc.)
- Drug and alcohol abuse
- Lack of patient compliance
- Poor circulation
- Hard physical labor or active sports
- Mental condition, which can lead to disregard of the medical order
- Highly atrophic jaw

IMPORTANT:
Attention must be paid to the protection of the anatomical structures (safety distance min. 2 mm) as well as to the course of the adjacent teeth / tooth roots (risk of damage, infection, resorption). To avoid infection and resorption, care should be taken to avoid contact between the graft and adjacent teeth. Mechanical stability is essential for successful bone healing.

SEPARATE NOTES FOR SCREWS:
The bone screws are compatible with the instruments of the Micro Screw System and Micro Screw System Basic. The screws may only be used with these system instruments. When selecting the screw length as well as the screw placement, the evaluation of the available bone by means of X-ray diagnostics must be taken into account. The screw head should be countersunk as flat as possible in the bone block to prevent soft tissue perforation or dehiscence. Excessive physical activity as well as trauma impairing the augmentation site can lead to premature failure of the screws due to loosening or breaking. The screws may only be used in accordance with the application and safety instructions. Any kind of modification in the procedure or on the product can lead to impairment of the success of the treatment or damage to the product. The screws are a disposable product and must therefore not be reprocessed and reused after use. Even with screws that have already been used but are visually undamaged, the previous mechanical stress can cause microscopic damage, which can lead to fatigue and product failure. The Micro Screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Micro Screws in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

Hager & Meisinger GmbH
Hansemannstr. 10
41468 Neuss • Germany
Tel. +49 2131 2012-0
Fax: +49 2131 2012-222
Email: info@meisinger.de
Internet: www.meisinger.de

Meisinger USA, L.L.C.
10150 E. Easter Avenue
Centennial, Colorado 80112 • USA
Phone: +1 (303) 268-5400
Fax: +1 (303) 268-5407
Email: info@meisingerusa.com
Internet: www.meisingerusa.com

Manufacturer | Sales partner | REF Item number | MD Medical device | LOT Batch number | Do not re-use | NON STERILE Non-sterile | Follow the instruction for use | Rx only Under U.S. federal law, this device may only be sold to or on behalf of trained medical professionals. | Manufacturing date | Caution, consult accompanying documents

Content

Micro Screw System

Art.-No. BMS00

1x 202RF 008	2x MSS10 040
1x 202RF 010	3x MSS10 060
1x MSPB1	3x MSS10 080
1x MSPB2	3x MSS10 100
1x MSSDW	2x MSS10 120
1x MSSDM	2x MSS10 140
1x MSGSD	1x MSS12 040
	2x MSS12 060
	2x MSS12 080
	2x MSS12 100
	1x MSS12 120
	1x MSS12 140

Micro Screw System Basic

Art.-No. BMSBA

1x 202RF 008	3x MSS10 060
1x 202RF 010	3x MSS10 080
1x MSPB1	3x MSS10 100
1x MSPB2	3x MSS12 060
1x MSSDE	3x MSS12 080
1x MSSDW	3x MSS12 100

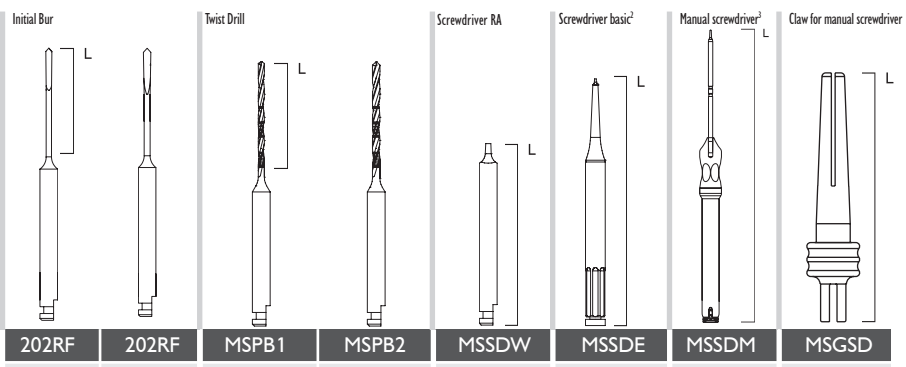


Fig.	202RF	202RF	MSPB1	MSPB2	MSSDW	MSSDE	MSSDM	MSGSD
Shank[1]	206	206	204	204	204	-	-	-
Size	008	010	008	010	-	-	-	-
Length mm	14.0	14.0	14.0	14.0	24.0	100.0	154.7	33.0
⏢	-	-	-	-	-	-	-	-
⏢	0.8	1.0	0.8	1.0	-	-	-	-
Opt. speed rpm	1.000	1.000	1.000	1.000	10	-	-	-
Max. speed rpm	6.000	6.000	6.000	6.000	15	-	-	
	CE 0044					CE		

[1] 204=RA , 206=RAXL
[2] illustrated 1:4
[3] illustrated 1:3

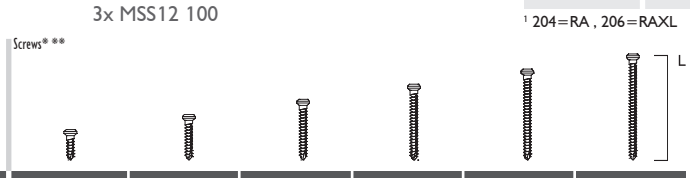


Fig.	MSS10 040	MSS10 060	MSS10 080	MSS10 100	MSS10 120	MSS10 140
Length mm	4.0	6.0	8.0	10.0	12.0	14.0
⏢	0.6	0.6	0.6	0.6	0.6	0.6
⏢	1.0	1.0	1.0	1.0	1.0	1.0
	CE 0044					

Fig.	MSS12 040	MSS12 060	MSS12 080	MSS12 100	MSS12 120	MSS12 140
Length mm	4.0	6.0	8.0	10.0	12.0	14.0
⏢	0.7	0.7	0.7	0.7	0.7	0.7
⏢	1.2	1.2	1.2	1.2	1.2	1.2
	CE 0044					

* Surgical stainless steel according to DIN ISO 5832-1, ASTM F138. For further information on alloy composition please contact the manufacturer.

** Do not re-use

⏢ External diameter ⏢ Minimal diameter

EN

Advice for processing (cleaning, disinfection and sterilisation) of MEISINGER Micro Screw System / Micro Screw System Basic

General Principles

All products are to be cleaned, disinfected, and sterilised prior to each application; this is required in particular for the first-time use after delivery of the unsterile instruments (cleaning and disinfecting after the removal of transport packaging; sterilisation of the single instruments only in FDA approved pouches or sterilization trays). An effective cleaning and disinfection is an indispensable requirement for an effective sterilisation of the instruments.
As you are responsible for the sterility of the products during use, please ensure

- that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilisation
- that the used devices (disinfector, sterilizer) are maintained and checked at regular intervals and
- that the validated parameters are adhered to during each cycle.

Cleaning and disinfecting

Basic rules:

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure must be considered. The pre-treatment step is to be performed in both cases.

Pre-treatment:

Abrasive impurities need to be removed from the products directly after use (within two hours maximum).

Procedure:

1. Disassemble the instruments as possible. Remove contaminated instruments from the metal box.
2. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F) If applicable. Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 5-10 ml). Sway movable parts at least three times during pre-rinsing.
3. Soak the disassembled instruments for the given soaking time in the pre-cleaning solution[1] so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush[2] and subsequent ultrasonic treatment (after brushing, for the minimum soaking time, but not less than 5 min). Sway movable parts at least three times during pre-cleaning.
4. If applicable: Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 5-10 ml).
5. Check the instruments on visible remnants. In case of still remaining remnants (e.g. bone or dentin particles) repeat steps 2 to 5, otherwise discard the instruments.

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature, and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

[1] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter "material resistance"). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

[2] Never clean products, bur blocks and sterilization trays using metal brushes or steel wool.

Automated cleaning/disinfection (disinfector/ WD (Washer-Disinfector)):

Please consider the following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA clearance)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices – at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying

If a WD is built in accordance with DIN EN ISO 15883 and regularly tested and maintained during its service life, it meets the above-mentioned requirements with regard to water and air quality.
When choosing an appropriate cleaning and disinfecting agent you need to ensure

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.
Procedure:

1. Disassemble the instruments as possible. Pre-cleaning of the instruments before sterilisation is recommended.
2. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact). If applicable: Connect the instruments to the rinsing port of the WD.
3. Start the program.
4. Disconnect (if applicable) and remove the instruments of the WD after end of the program.
5. Check and pack the instruments immediately after the removal (see chapters "check", "maintenance", and "packaging", if necessary after additional post-drying at a clean place). The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher mediclean forte (5 min at 95° C) (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Manual cleaning and disinfection:

When choosing an appropriate cleaning and disinfecting agent you need to ensure

- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking) compatible with the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Combined cleaning/disinfection detergents should not be used. Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used. Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Cleaning:

1. Disassemble the instruments as possible. Pre-cleaning is recommended for the instruments before sterilization (see specific dismantling instructions).
2. Soak the disassembled instruments for the given soaking time in the cleaning solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush[1] and subsequent with ultrasonic treatment (after brushing, for the minimum soaking time, but not less than 5 min). Sway movable parts at least three times during cleaning. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
3. Then, remove the instruments of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Sway movable parts at least three times during post-rinsing. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
4. Check the instruments (see chapters "check" and "maintenance").

[1] Never clean products, bur blocks and sterilization trays using metal brushes or steel wool.

Disinfection:

5. Soak the disassembled instruments for the given soaking time in the dis-infectant solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Sway movable parts several times during disinfection. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
6. Then, remove the instruments of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water. Sway movable parts at least three times during post-rinsing. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
7. Dry and pack the instruments immediately after the removal (see chapter "packaging", if necessary after additional post-drying at a clean place). The fundamental suitability of the instruments for an effective cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the cleaning detergent Gigazyme (5 min with 5% solution) and the disinfectant Gigasept Instru AF (15 min with 3% solution) (Schülke & Mayr GmbH, Norderstedt) considering the specified procedure.

Checking

After all products have been cleaned and/ or cleaned/disinfected, check them for corrosion, damaged surfaces/ bare patches, broken/ chipped-off edges, deformations (e.g. bent rather than round) and impurities and eliminate damaged products. Products that are still contaminated need to be cleaned and disinfected once more.

Maintenance

- Re-assemble disassembled products (see specific instructions).
- Instrument oils must not be used.

Packaging

Please insert the cleaned and disinfected products in the dedicated bur block/metal box. Please only use sterilization trays, single-use sterilization packagings (single or double packaging) and/ or sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)
- Individual packaging: the packaging must be sufficiently large to ensure that the sealing is tension-free.

Sterilisation

We only recommend the use of the sterilisation procedures listed below.
Steam sterilization:

- fractionated vacuum/dynamic air removal procedure[1] (with sufficient product drying[2])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- sterilization time (exposure time at the sterilization temperature): at least 4 min at 132 °C (270 °F), drying time at least 20-30 min

[1] at least three vacuum steps

[2] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer ZentraCert (Lautenschläger GmbH & CO. KG, Cologne) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor´s practice as well as the specified procedure were considered. The flash/ immediate use sterilization procedure must not be used. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Prior to the first use of the device, the product should be stored in its original packaging at room temperature in dust- and humidity-free conditions. Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity and recontamination). After sterilisation, the products need to be stored in sterilization wrapping in a dry and dust-free place. Please note the shelf-life resulting from the validation of the sterilisation wrapping.

Material resistance

When choosing the cleaning and disinfecting agents ensure that they do not contain the following ingredients:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline or alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments. Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool. Please do not expose any instruments and sterilization trays to temperatures higher than 138 °C (280 °F)!