REF: MZZ-1 Fastening Device for Ball-Joint Adapter

MZZ-1Q Fastening Device for Ball-Joint Adapter, flat foot

Ball-joint adapter (variable length/height):	**Accessories:**
REF **MRV-9F** ..... straight D 4 mm	Cardan screwdriver **LMT-4**
MRV-1F ..... straight D 6,35 mm	
MRZ-9..... straight D 8 mm	
MRU-8F ..... bayonet D 4 mm	
MRV-0F ..... bayonet. D 6,35 mm	
MRV-0S ..... bayonet D 6,35 mm	
MRV-0J ..... bayonet w/ hinge D 6,35 mm	
MRV-0R..... bayonet w/ hinge D 6,35 mm	

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The fastening device may only be used, reprocessed and disposed of by competent medical personnel!

The fastening device and the ball-joint adapter are intended for transient use (< 60 min.).

Intended use:

The fastening device MZZ-1/1Q is intended for the connection to ball-joint adapters which can be attached to retractors variably in relation to height and length.

The ball-joint adapter is intended to hold instruments with a cylindrical shaft with a diameter of 4 mm, 6,35 mm or 8 mm.

Indications and contraindications

Indications:	Contraindications:
Ball-joint adapters and fastening devices are used in combination with parallel retractors, preferably during minimally invasive surgery.	Not known.

Prior to use:

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The fastening device and the ball-joint adapters are delivered non-sterile and must be cleaned and sterilized by the user prior to initial and all further uses (see Reprocessing).

The fastening device and the ball-joint adapters must be handled with care during storage, transportation and cleaning. Avoid striking the devices or applying pressure to only parts of it!

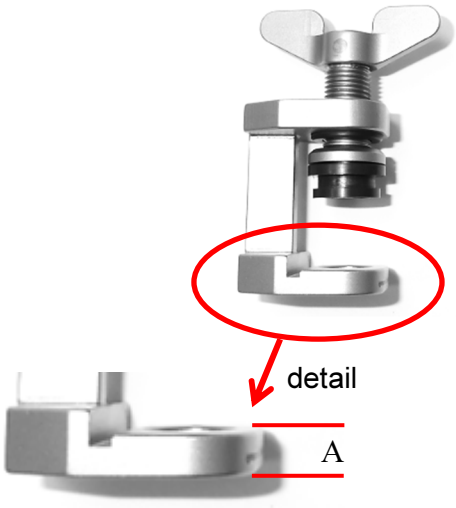
Perform a safety check prior to each use. Check for cracks or fractures (see also Maintenance, Control and Functional Testing).

Use only flawless and sterilized products!

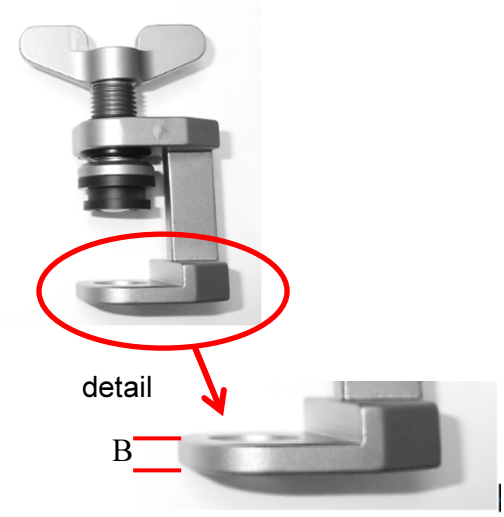
Components:

Ball-joint adapters like the ones mentioned above, can be attached to parallel retractors with a rack thickness of 4.8 mm to 10 mm using the fastening device MZZ-1/1Q.

Fastening devices:



Fastening device **MZZ-1**
Foot height A: 5 mm



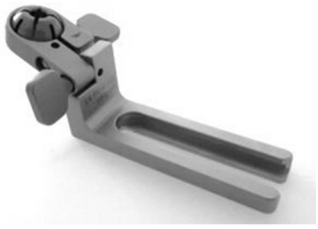
Fastening device **MZZ-1Q**
Foot height B: 3,5 mm

Examples for the selection of ball-joint adapters:

Ball-joint adapter
for instruments with a cylindrical shaft
MRV-9F ∅ 4 mm
MRV-1F ∅ 6,35 mm
MRZ-9 ∅ 8 mm

Ball-joint adapter, bayonet,
for instruments with a cylindrical shaft
MRU-8F ∅ 4 mm
MRV-0F ∅ 6,35 mm
MRV-0S ∅ 6,35 mm

Ball-joint adapter, bayonet,
for instruments with a cylindrical shaft,
angle adjustable using Cardan screwdriver LMT-4
MRV-0J ∅ 6,35 mm

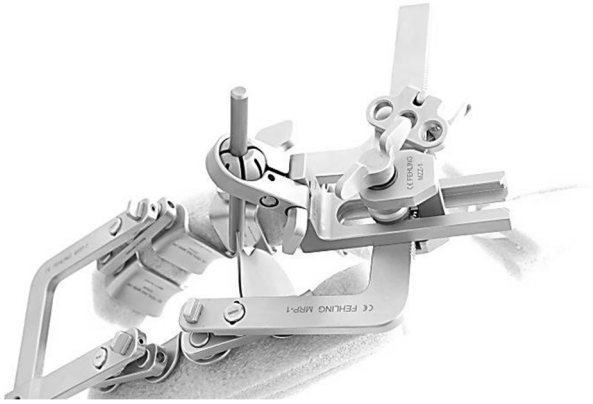
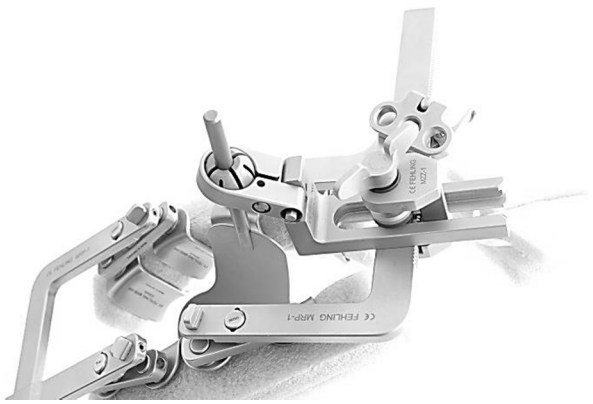


Ball-joint adapter, bayonet,
for instruments with a cylindrical shaft,
angle adjustable with wing bolt
MRV-0R ∅ 6,35 mm

Accessory: Cardan screwdriver LMT-4

During use:		
		
Lateral view: Fastening device is slid onto the adapter rail	Attachment to the retractor arm with a 45° angle	Connection is fastened by tightening the bolt screw

⚠	The ball-joint adapter and the fastening device are attached loosely to each other. Take care to hold both parts firmly during handling, to prevent inadvertend slipping or dropping of a part.

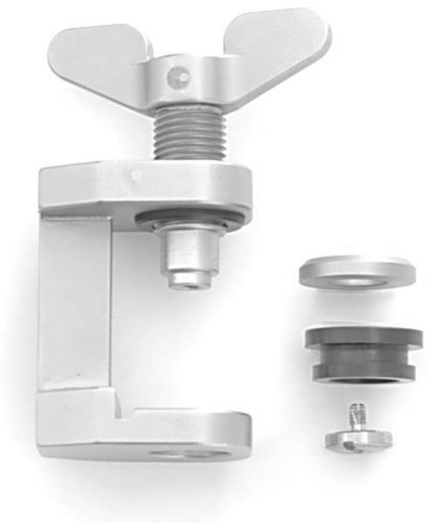
Operation of the ball-joint adapter with a wing bolt	Operation of the ball-joint adapter with a Cardan screwdriver
	

Reprocessing instructions:

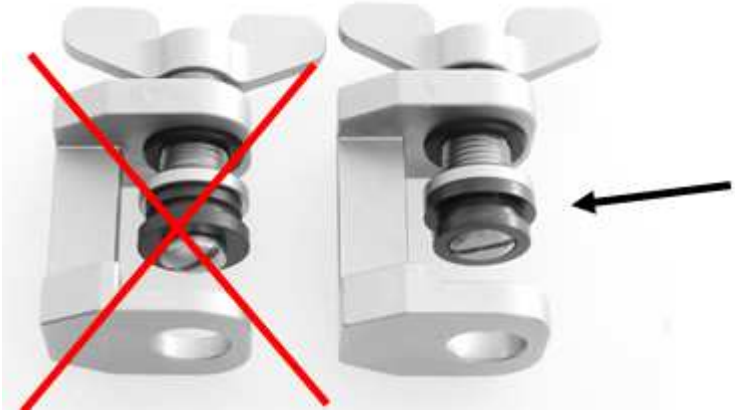
Restriction for reprocessing:

Frequent reprocessing has only minor effects on these instruments. Usually the end of the product service life is determined by wear and damage from use (see “Control and Function Test” for details).

Place of application:	Remove surficial contamination with a single-use cloth/towel- - Pre-cleaning
Storage: according to § 4 MPBetreibV (regulation on the operation of medical devices)	Store instruments in a dry place to avoid condensation. It is recommended to reprocess the instruments immediately after use, because it is very difficult to remove dried residues from instrument parts that are difficult to access.

Disassembly of the fastening device for cleaning:	 The fastening device is disassembled using an appropriate slotted screwdriver. After loosening the screw and disassembly, the guide washer (PEEK) and the pressure disk (steel) can be removed from the wing screw by hand.
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not immerse in normal saline (NaCl) solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemicals manufacturer's recommendation for the mixture). Avoid overfilling instrument trays and washing trays – use only suitable instrument holders. When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck anywhere.. Always open and/or disassemble joint instruments for processing. Release the springs if necessary.
Cleaning/Disinfection according to DIN EN ISO 15883-1:2009	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with. If available, the use of a washer/disinfector unit which uses thermal disinfection is recommended.
Cleaning/disinfection: **mechanically** **acc. to standard** **EN ISO 15883-1:2009**	<u>Validated Procedure:</u> Equipment: Washer/disinfector Miele G7836 CD Process: 2-component alkaline/enzymatic Cleaning Agents: deconex TWIN PH 10 and deconex TWIN ZYME (Borer, Switzerland) <u>Preparation</u>: • Joint instruments are to be placed in the device such that the hinge is open and that water can flow off cavities and blind holes. • Make sure that all cavities are completely flushed on the inside as well.

	• Make sure that no flushing shadows arise. Parameters: • 3 min pre-cleaning with tap water • Drain • 10 min cleaning with tap water 0,3 % dosing TWIN PH10 at 35 °C (95°F) and 0,2 % dosing TWINZYME at 40 °C (104°F) • Drain • 2 min rinsing with deionized water > 30 °C (86°F) • Drain • 1 min rinsing with deionized cold water • Drain • 5 min thermal disinfection at 93 °'C (200°F) • After mechanical cleaning, check cavities, blind holes, etc. for visible dirt. Repeat cycle or clean manually if required. • Other locally validated methods, including those specified in HTM2030, may be used.
Cleaning/disinfection: manually	Validated procedure Equipment: Bandelin Sonorex RK 1028 H Detergents: Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz. After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products. Disinfection: Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (at least 5 min. at 93 °C). (Thermal disinfector, see instructions of the device manufacturer.) Demineralizerd water must be used for the final rinsing step. Make sure that no residues remain on the products.

Assembly:	Assembly of the fastening device is performed in three steps: • Mount pressure disc (steel) onto the screw thread, champfer at the head • Mount the guide washer (PEEK) onto the pressure disc; the side with the larger diameter must point to the pressure disc • Screw on the fastening screw using an appropriate slotted screw-driver CAUTION: The disc/washer must not be mounted in a different way, as otherwise, the function of the fastening devices cannot be ensured (see picture below)  **WRONG! RIGHT!**
Drying:	If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Maintenance:	Apply a small amount of high-grade, water-soluble instrument spray onto all movable parts. Sort out blunt or damaged instruments (check for cracks or damage). Verify usability.
Control and function test:	Check joint instruments for easy operation (avoid too much play). Check locking mechanisms. All Instruments: Use a magnifying lamp to visually inspect the components for damage and wear and tear. Edges should not show nicks and should be even. Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.
Packaging:	Single: in accordance with the standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately.

Sterilization:	Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. Validated procedure: Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: at least 10 minutes
Storage:	In accordance with §4 of the Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.

Storage / Symbols

Store in a dry place!	Protect from excessive heat!	Follow the instructions for use	Article number	Lot number
Manufacturer	CE marking	Warning		

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