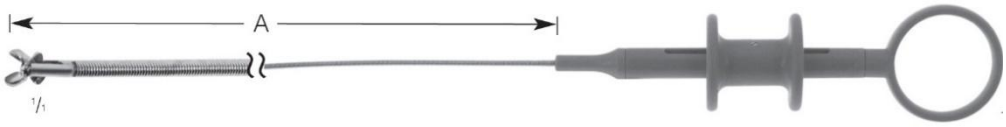
Disposable Myocardium Biopsy Forceps, sterile	
REF: **Description:**	**REF:** **Description:**
MOA-1.... Single-use biopsy forceps, sterile, 1.6 × 510 mm	MOA-6 ... Single-use biopsy forceps, sterile, 1.8 × 800 mm
MOA-2.... Single-use biopsy forceps, sterile, 1.6 × 800 mm	MOA-7 ... Single-use biopsy forceps, sterile, 1.8 × 1,000 mm
MOA-3.... Single-use biopsy forceps, sterile, 1.6 × 1,000 mm	MOA-8 ... Single-use biopsy forceps, sterile, 1.8 × 1,200 mm
MOA-4.... Single-use biopsy forceps, sterile, 1.6 × 1,200 mm	MOA-9 ... Single-use biopsy forceps, sterile, 2.2 × 510 mm
MOA-5 …Single-use biopsy forceps, sterile, 1.8 × 510 mm	MOB-1….Single-use biopsy forceps, sterile, 2.2 × 1,200 mm
Rx only	CAUTION: U. S. A Federal law restricts this device to sale by or on the order of a physician
This instruction does not substitute reading the instructions for use of the employed accessories.	

1) Warnings and precautions	
	Single use, Do not process - do not reuse! Dispose of the biopsy forceps according to the regulations in the collecting box for used disposable products in the operation theatre.
	Do not use products from damaged packaging and return them to the manufacturer! Do not use products whose expiration date has passed! Risk of infection!
	Use only perfect and sterilized products! Always handle biopsy forceps with care! Risk of damage → Risk of injury!
	Do not store under +5°C and over +40°C for prolonged periods! Observe expiration date! Do not use after expiration date!
	The biopsy forceps shall only be used by cardiologists or heart surgeons with support by personnel with special training and if indicated and if there are no contraindications. Myocardium biopsy forceps shall only be used and disposed of by competent medical personnel!
	The procedure must be performed under radiographic control in order to reliably move the distal end of the instrument into the ventricle. – Failure to do so may result in injury!
	Biopsy forceps are precise mechanical products. Please always handle with care! Risk of damage! Risk of injury!
	For pre-shaping the distal part, place it on both thumbs and then use the index fingers to bend the shaft across the two thumbs! Do not kink! Risk of immobility → Risk of injury! Do not bring any load on the connection area of shaft and functional (distal) end – Risk of breakage → Risk of injury! Perform a function test after pre-shaping.
	After obtaining the tissue sample, keep the spoons of the biopsy forceps closed until the forceps have been removed from the body and the sample is recovered. → Risk of embolism if the specimen is lost!

2) Device description



Length of shaft "A"	1,6 mm	1,8 mm	2,2 mm
510 mm	MOA-1	MOA-5	MOA-9
800 mm	MOA-2	MOA-6	–
1000 mm	MOA-3	MOA-7	–
1200 mm	MOA-4	MOA-8	MOB-1

The biopsy forceps are designed to allow percutaneous access to the right or left ventricles of the heart in order to obtain diagnostic tissue samples. At the distal end of the forceps is a pair of stainless-steel jaws used to obtain the heart tissue samples. At the proximal end of the forceps is the actuation handle used to activate the jaws and steer the device.

3) Intended purpose

FEHLING Biopsy Forceps are used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.

Additional information about the intended purpose

The myocardium biopsy forceps are sterile single-use products. They are intended to be used only for separating and removing soft tissue samples.

Duration of application: The myocardium biopsy forceps are intended for temporary use.

Area of application: The myocardium biopsy forceps are used for all patients for removal of tissue samples for histological examination.

User profile: Myocardium biopsy forceps may only be used by medically trained personnel (e.g., specialists).

Application environment: Myocardium biopsy forceps may only be used in controlled environments (e.g., OR).

4) Contraindications

- Secondary involvement in diagnosed systemic diseases such as sarcoidosis, amyloidosis or hemochromatosis
- Neoplasia: e.g. myxoma, rhabdomyoma, sarcoma or metastases
- Cardioneuropathy: e.g. progressive muscular dystrophy
- Toxic cardiomyopathy: e.g. due to cytostatics
- Cardiac tumors
- Coronary heart disease
- Mechanical valve replacement of the heart valve through which the forceps are to be passed
- Intracardiac thrombus

4) Contraindications

All applications that run counter to the physical and/or mechanical properties of the individual biopsy forceps model are contraindicated. Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient (e.g. ventricular aneurysm, severe tricuspid, pulmonary or aortic stenosis).

5) Possible adverse effects of endomyocardial biopsy (EMB)

In the medical literature, the following adverse effects are described for endomyocardial biopsy (EMB) that can also occur during the intended use of FEHLING biopsy forceps:

- Perforation of heart tissue and vessels, which can result in: Local hematoma / Pseudoaneurysms / Hemothorax / AV-fistula / Hemopericardium / Cardiac or pericardial tamponade
- Polarization and conduction disorders
- Persistent bleeding
- Damage to the passed valves
- Arrhythmia
- Blood pressure drop or increase / chest pain / dyspnea
- Pneumothorax
- Cerebrovascular complications
- Embolism / thrombus
- Vasovagal response
- Infections
- Allergic reactions

As for adults, the decision to perform an EMB in children can only be made by the attending physician after considering all the benefits and risks.

6) Directions for use

The procedure is similar to that of a conventional cardiac catheter examination; usually endomyocardial biopsies are executed within the scope of a cardiac catheter examination that was performed anyway, in the cardiac catheter laboratory. For the rejection diagnosis the endomyocardial biopsy from the right ventricle has proven to be the method of choice.

⚠	Check sterility and packaging for integrity! Using products from damaged packaging is associated with the risk of infection! Do not use products from damaged packaging and return them to the manufacturer! Do not use products whose expiration date has passed! Risk of infection! Do not use products from inadvertently opened packaging and dispose of them properly! Observe the use-by date! Do not use products after the indicated use-by date and dispose of them properly! Danger of infection!
	Check function of biopsy forceps by opening and closing several times! Biopsy forceps are precision products. Please always handle with care! Danger of breakage → Danger of injury!

	Visually inspect biopsy forceps for sharp edges and damage!
	Use only perfect and sterilized products!

Choose appropriate introducer sheaths

We recommend using the introducer sheaths for the jaw diameter sizes listed:

Jaw	Introducer sheath inner Ø
1,6 mm	5 F
1,8 mm	6 F
2,2 mm	7 F
2,2 mm	8 F

The procedure must be performed under radiographic control in order for the distal end of the instrument to be taken to the removal site reliably.
Failure to do so may result in injury.

To enable the access of the cutting end of the biopsy forceps to any location of the ventricle, bend the distal tip within 20 – 50 mm from the distal end of the device.

⚠	Do not apply excessive force to the connection of the shaft and distal (functional) end of the forceps – Risk of breakage → Risk of injury!
⚠	For pre-shaping the distal part, place it on both thumbs and then use the index fingers to bend the shaft across the two thumbs! Do not kink! Risk of immobility → Risk of injury! Perform a function test after pre-shaping.

Right Ventricular Biopsy	Left Ventricular Biopsy
Once disinfection and local anesthesia of the puncture location is performed, a sheath is introduced in the vein (femoral vein, jugular vein) according to Seldinger.	Once disinfection and local anesthesia of the puncture location is performed, a sheath is introduced in the artery (femoral artery) according to Seldinger.
Close spoon by relaxing the handle components, then insert the biopsy forceps through the venous system into the ventricle	Close spoon by relaxing the handle components, then insert the biopsy forceps through the artery system into the ventricle
⚠ Risk of injury to the vessel walls if spoons are open! Advance the biopsy forceps into the working channel slowly, carefully and without any use of force. Do not kink! → Risk of injury!	
Move forward through the vena cava with biopsy forceps to the level of the right atrium, pass through the tricuspid valve and take samples from the ventricle walls.	Move forward through the aorta with biopsy forceps, pass through the aortic valve and take samples from the ventricle walls.

After taking the sample, make sure to keep the spoons of the biopsy forceps closed until the biopsy forceps have been removed from the body and the sample shall be recovered.

⚠ → Risk of embolism if the specimen is lost! Removal of forceps should be performed immediately after obtaining each sample.
This procedure can take 15 – 30 minutes and in exceptional cases, it can take longer. After the procedure, apply pressure to the puncture location to prevent bleeding and cover the site with a dressing.

7) After use	
	Dispose of the biopsy forceps according to the regulations in the collecting box for used disposable products in the operation theatre. Do not process, do not reuse! – Disposable product – risk of infection!

8) Storage
Do not store under +5°C and over +40°C for prolonged periods. Observe expiration date. Do not use after expiration date.

9) Requirements for Reporting Serious Incidents
The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or using the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user resides.

10) Symbols	
CE 0297	CE sign with notified body, indicates that the medical device has been tested and that it passed the conformity assessment procedure from the EU harmonization legislation.

Symbols standard of origin: ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:

STERILE EO (5.2.3)	Sterilized using ethylene oxide; indicates a medical device that has been sterilized using ethylene oxide.	(5.4.3)	Consult instructions for use; indicates the need for the user to consult the instructions for use.
LOT (5.1.5)	Batch code; indicates the manufacturer's batch code so that the batch or lot can be identified.	REF (5.1.6)	Catalog number; indicates the manufacturer's catalog number so that the medical device can be identified.

 (5.4.4)	Caution; indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	 (5.4.2)	Do not re-use; indicates a medical device that is intended for one single use only.
 (5.2.8)	Do not use if package is damaged and consult instructions for use; indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for use for additional information.	 (5.3.4)	Keep dry; indicates a medical device that needs to be protected from moisture.
 (5.3.2)	Keep away from sunlight; indicates a medical device that needs protection from light sources.	 (5.1.4)	Use-by date; indicates the date after which the medical device is not to be used.
 (5.2.11)	Single sterile barrier system; indicates a single sterile barrier system.	 (5.2.12)	Double sterile barrier system; indicates two sterile barrier systems.
 (5.1.3)	Date of manufacture; indicates the date when the medical device was manufactured.	 (5.7.10)	Unique device identifier; indicates a carrier that contains unique device identifier information.
 (5.7.7)	Medical device; indicates the item is a medical device.		
 (5.1.1)	Manufacturer; indicates the medical device manufacturer FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100, 63791 Karlstein, Germany Tel.: +49 (0) 6188 - 957440 Fax: +49 (0) 6188 - 957445 www.fehling-instruments.de		