FEHLING Sterile Myocardial Biopsy Forceps for Single Use	
MOA-1 ... Single-use biopsy forceps, sterile, 1.6 × 510 mm MOA-2 ... Single-use biopsy forceps, sterile, 1.6 × 800 mm MOA-3 ... Single-use biopsy forceps, sterile, 1.6 × 1,000 mm MOA-4 ... Single-use biopsy forceps, sterile, 1.6 × 1,200 mm MOA-5 ... Single-use biopsy forceps, sterile, 1.8 × 510 mm MOA-6 ... Single-use biopsy forceps, sterile, 1.8 × 800 mm	MOA-7 ... Single-use biopsy forceps, sterile, 1.8 × 1,000 mm MOA-8 ... Single-use biopsy forceps, sterile, 1.8 × 1,200 mm MOB-4 ... Single-use biopsy forceps, sterile, soft, 1.8 × 510 mm MOB-5 ... Single-use biopsy forceps, sterile, soft, 1.8 × 1,200 mm MOA-9 ... Single-use biopsy forceps, sterile, 2.2 × 510 mm MOB-1 ... Single-use biopsy forceps, sterile, 2.2 × 1,200 mm
	The myocardial biopsy forceps are a single-use product and must not be processed and reused. Due to the instrument's mechanics, proper processing cannot be guaranteed.

	The myocardial biopsy forceps may only be used by cardiologists or cardiac surgeons supported by trained qualified personnel, and if indicated and if there are no contraindications. The myocardial biopsy forceps may only be used and disposed of by qualified medical personnel!

1) Intended purpose

FEHLING biopsy forceps are intended to be used to remove tissue samples for histological examination, specifically for endomyocardial biopsy.

Additional information about the intended purpose

The myocardial 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 myocardial biopsy forceps are intended for temporary use.

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

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

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

Intended patient population: Myocardial biopsy forceps are intended for use in children weighing 10 kg or more and adults.

2) Indications

- Diagnosing inflammatory cardiomyopathy, follow-up, and differential diagnostics
- Suspected inflammatory cardiovascular pathogenesis
- Existing dilated cardiomyopathy (to exclude myocarditis)
- Differential diagnostics: confirmation or exclusion of myocardial involvement, e.g., within a systemic disease

3) Contraindication

- Secondary involvement with 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

4) 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 Myocardial Biopsy Forceps:

- Right ventricular perforation / arterial puncture / AV fistula
- Pericardial tamponade
- Polarization and conduction disorders
- Arrhythmia
- Persistent bleeding from the vessel puncture site, local hematoma / pseudoaneurysm
- Allergic reactions
- Neurological complications or pulmonary embolism (due to the transport of tissue particles, release of artherosclerotic plaques or small blood clots)
- Tricuspid valve regurgitation resulting from frequently repeated endomyocardial biopsies (in cardiac transplant patients)
- Vasovagal response
- Decrease/increase in blood pressure, chest pain, respiratory distress

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.

⚠	Medical devices may contain, e.g., chromium and/or nickel. The materials used are biocompatible; however, they may cause allergic reactions or incompatibilities.

5) Prior to use

⚠ 🚫	Check sterility and packaging for integrity! If products from damaged packaging are used, there is a danger of infection! Do not use products from damaged packaging and return them to the manufacturer! 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 return to the manufacturer! Danger of infection!
⚠	Perform a safety check before each use. Check that the myocardial biopsy forceps function correctly by opening and closing them several times! Visually inspect myocardial biopsy forceps for sharp edges and damage!
⚠	Only use sterilized products that are free of defects!
⚠	Handle myocardial biopsy forceps with care when storing and transporting! Do not strike or apply pressure to the myocardial biopsy forceps to prevent any resulting damage! Do not overstrain functional parts!
⚠	Myocardial biopsy forceps are precision products. Please always handle with care! Danger of breakage → Danger of injury!

For the external jaw diameters listed here, the particular internal sheath diameter stated is recommended:

For jaw width	Internal sheath diameter
1.6 mm	5 F
1.8 mm	6 F
2.2 mm	7 F
2.2 mm	8 F

6) Configuration and application

Endomyocardial biopsy, also referred to conventionally as a biopsy, is the removal of a sample of heart muscle for histological examination. The aim of this examination is to determine the cause of distinct cardiac muscle diseases not caused by hypertension, coronary vessel diseases, or heart defects, follow-up of such a disease, or after a heart transplant (diagnosis of rejection).

Worldwide, endomyocardial biopsy is the most widely used procedure for diagnosing rejection reactions after heart transplants.

Due to the introduction of new techniques from molecular biology, immunology, and virology and the associated improvement in the diagnostic and differential diagnostic options for inflammatory heart muscle diseases, the diagnostic benefit of endomyocardial biopsy has increased greatly in recent decades because heart muscle biopsy can confirm these diagnoses.

The myocardial biopsy forceps are made up of a long, flexible shaft (a) with an internal pushing/pulling wire, sharp spoons (b) on the distal end (Fig. 1a), and a ring handle (c) (Fig. 1b) on the proximal end. By pushing the ring-shaped parts of the handle section (d) together or apart, the spoons (b) can be closed or opened over the internal sheath running along the shaft (a).

Due to the diversity of anatomical and physiological conditions that are possible, myocardial biopsy forceps differ in their specific characteristics, such as the length and design of the shaft or the jaw width.

Fig. 1a: Distal working end of the myocardial biopsy forceps, open (greatly magnified)

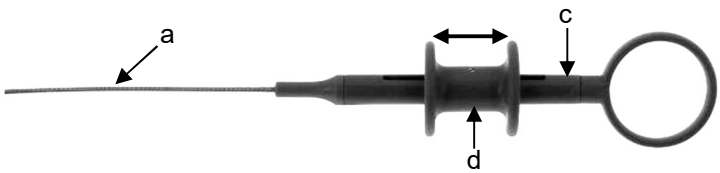

Fig. 1b: Ring handle of the myocardial biopsy forceps, proximal end

In the relaxed state of the handle, the spoons are closed (Fig. 2a).

To open the spoons (Fig. 2b), push the ring-shaped part of the ring handle (Fig. 1b) toward the shaft. By pressing the ring-shaped parts of the handle together, the spoons close (Fig. 2b). The tissue (biopsy) located between the spoons is severed by the sharpened edges, is held inside the spoons, and can be safely removed from the collection site.

Fig. 2a: Closed spoons

Fig. 2b: Opened spoons

⚠	Only use sterilized products that are free of defects!
⚠	Before using the myocardial biopsy forceps, ensure that the surgical field has first been prepared appropriately.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of myocardial biopsy forceps depends on the anatomical and physiological conditions as well as the field of application. Take care to ensure that the myocardial biopsy forceps used are of the correct size and sufficiently stable.

During use

The procedure is analogous to the conventional cardiac catheter examination; endomyocardial biopsies are usually performed in the cardiac catheter laboratory as part of a cardiac catheter examination that would have taken place anyway.

⚠	The procedure must be performed under radiographic control to ensure that the distal end of the instrument is reliably taken to the removal site. – Failure to do so may result in injury!

After disinfection and local anesthesia of the puncture site, a sheath is inserted into a vein (right ventricle biopsy: femoral vein, jugular vein) or an artery (left ventricle biopsy: femoral artery) according to Seldinger.

The technique involves, after disinfection and local anesthesia of the puncture site, the puncture of the right jugular vein or femoral vein into which a Seldinger sheath is inserted. The myocardial

biopsy forceps are then guided through the vena cava up to the level of the right atrium, passed through the triscuspid valve, and then used to collect samples from the interventricular septum.	
⚠	Limit the pre-bending of the distal part of the shaft to the distal 25 to 50 mm section! Keep a minimum radius of 12–15 mm. To pre-bend the shaft, 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 → Danger of injury! Do not subject the connection area between the shaft and the articulated arms to bending stresses – Danger of breakage → Danger of injury! Perform a function test after pre-bending.
⚠	Only insert the myocardial biopsy forceps through the vessel system into the ventricle with the spoon closed, i.e., with relaxed handle parts! → Risk of injury to the vessel walls if spoons are open! Advance the myocardial biopsy forceps into the working channel slowly, carefully, and without applying any force. Do not kink! → Danger of injury!
⚠	After the procedure, immediately remove the myocardial biopsy forceps from the working channel. After taking the sample, make sure to keep the spoons of the myocardial biopsy forceps closed until the myocardial biopsy forceps have been removed from the body and the sample can be recovered. → Risk of embolism if the specimen is lost!
After use	
⊘	Do not process and do not re-use! Single-use product – danger of infection if reused!
⚠	Dispose of the myocardial biopsy forceps in accordance with the hospital's internal regulations for infectious waste!

7) Storage

In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.

Instruments must be stored dry, at room temperature, clean, and protected from damage, sunlight and mechanical influences (avoid condensation, damage).

⌛	Observe the use-by date! Do not use products after the indicated use-by date and return them to the manufacturer!

8) Required Accessories

No accessories are required for using the myocardial biopsy forceps.

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.

Symbols		
If there are images on the medical device or medical device label or the instructions for use, the symbols have the following meaning as defined in DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical Device	UDI Unique Device Identifier	STERILE EO Sterilized using ethylene oxide
Use-by date	Date of manufacture	Single sterile barrier system
Double sterile barrier system	Keep dry	Keep away from sunlight
Do not use if package is damaged and consult instructions for use	Do not re-use	CE 0297 CE marking
Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.		

To contact the manufacturer:	
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