FEHLING sterile myocardial bioptomes single-use device	
MOA-1 Single-use sterile bioptome, 1.6 x 510 mm MOA-2 Single-use sterile bioptome, 1.6 x 800 mm MOA-3 Single-use sterile bioptome, 1.6 x 1,000 mm MOA-4 Single-use sterile bioptome, 1.6 x 1,200 mm MOA-5 Single-use sterile bioptome, 1.8 x 510 mm MOA-6 Single-use sterile bioptome, 1.8 x 800 mm	MOA-7 Single-use sterile bioptome, 1.8 x 1,000 mm MOA-8 Single-use sterile bioptome, 1.8 x 1,200 mm MOB-4 Single-use sterile bioptome, soft, 1.8 x 510 mm MOB-5 Single-use sterile bioptome, soft, 1.8 x 1,200 mm MOA-9 Single-use sterile bioptome, 2.2 x 510 mm MOB-1 Single-use sterile bioptome, 2.2 x 1,200 mm

	The myocardial bioptome is a single-use device and must not be reprocessed or re-used. Due to the mechanics of the instrument, proper reprocessing cannot be guaranteed.

	The myocardial bioptomes may only be used by cardiologists or cardiac surgeons, with the assistance of trained medical staff, when there is an established indication and in the absence of contraindications. The myocardial bioptomes may only be used and disposed of by qualified medical staff!

(1) Intended purpose

FEHLING bioptomes are designed for taking tissue samples for histologic examination, especially endomyocardial biopsy.

Supplementary information on the intended purpose

Myocardial bioptomes are sterile single-use device. They are intended exclusively for separating and removing soft tissue samples.

Duration of application: The myocardial bioptome is intended for temporary use.

Field of application: Myocardial bioptomes are used in all patients where tissue samples need to be taken for histological examination.

User profile: Myocardial bioptomes may only be used by medically trained specialists (e.g. medical specialists).

Application environment: Myocardial bioptomes are used only under controlled environmental conditions (e.g. surgery).

Anticipated patient population: Myocardial bioptomes are intended for use in children from 10 kg and for adults.

2) Indications

- Diagnosis, monitoring and differential diagnosis of inflammatory cardiomyopathy.
- Suspicion of an inflammatory origin of the heart disease.
- Presence of dilated cardiomyopathy (to rule out myocarditis).
- Differential diagnostics: Clarification of myocardial involvement, e.g. in the context of a systemic disease.

3) Contraindication

- Secondary involvement in systemic diseases: e.g. sarcoidosis, amyloidosis, hemochromatosis.
- Neoplasia: e.g. myxoma, rhabdomyoma, sarcoma, filia.
- Cardioneuropathies: e.g. progressive muscular dystrophy.
- Toxic cardiomyopathy: e.g. due to cytostatic drugs.
- Heart tumors
- Coronary heart disease
- Mechanical heart valve to replace the heart valve to be passed.

4) Possible side effects of an endomyocardial biopsy (EMB)

The following side effects are described in the medical literature for endomyocardial biopsy (EMB), which may also occur during the intended purpose of myocardial bioptomes:

- Perforations of the heart wall / ventricular perforation / arterial puncture / AV fistulas
- Pericardial tamponade
- Disorders of excitation formation and conduction
- Arrhythmias
- Persistent bleeding from the vascular puncture site, local hematoma / pseudoaneurysms
- Allergic reactions
- Neurological complications or pulmonary embolism (due to the entrainment of tissue particles, dissolution of atherosclerotic plaques or small blood clots)
- Tricuspid valve damage as a result of frequently repeated endomyocardial biopsies (in patients after heart transplants)
- Vasovagal reactions
- Drop/increase in blood pressure, chest pain, shortness of breath

The decision to perform an EMB in children – as in adults – can only be made by the treating physician after weighing all the pros and cons.

⚠	For example, medical devices may contain chromium and/or nickel. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use

⚠ 🚫	Check the sterile packaging for damage! There is a risk of infection when using products from damaged packaging! Do not use products from damaged packaging and return them to the manufacturer! Do not use products from packaging that has been opened accidentally. Dispose of them properly!

	Note the expiry date! Do not use products after the specified expiry date and return them to the manufacturer! Risk of infection!
⚠	A safety inspection must be carried out before each use. Check the functionality of the myocardial bioptomes by opening and closing them several times! Visually inspect the myocardial bioptomes for sharp edges and damage!
⚠	Only use flawless and sterilized products!
⚠	Handle the myocardial bioptomes with care during storage and transport! Avoid impacts and localized pressure on the myocardial bioptomes in order to prevent possible consequential damage! Do not overload functional parts!
⚠	Myocardial bioptomes are high-precision mechanical products; please always handle them with care! Risk of breakage! →Risk of injury!

Outer diameters of the jaws listed below are recommended for the corresponding inner air-lock diameters:

For jaw width	Airlock diameter inside
1.6 mm	5 F
1.8 mm	6 F
2.2 mm	7 F
2.2 mm	8 F

6) Configuration and application

An endomyocardial biopsy, also known as a "biopsy" in everyday language, is the removal of a heart muscle sample for histological examination. The aim of this examination is to determine the cause of independent heart muscle diseases that are not caused by high blood pressure, coronary artery disease or heart defects, to monitor the course of such a disease or after a heart transplant (rejection diagnostics).

Worldwide, endomyocardial biopsy is used most frequently in the diagnosis of rejection reactions following heart transplantation.

The diagnostic value of endomyocardial biopsy has greatly increased in recent decades due to the introduction of new techniques in the fields of molecular biology, immunology and virology and the associated improvement in the diagnostic and differential diagnostic possibilities of inflammatory myocardial diseases, because myocardial biopsy can be used to confirm these diagnoses.

The myocardial bioptome consists of a long, flexible shaft (a) with an internal push/pull wire, sharp jaws (b) on the distal (Fig. 1a) and a pull-roller handle (c) (Fig. 1b) at the proximal end. By pressing the ring-shaped handle part (d) of the pull-roller handle (c) together or apart, the jaws (b) can be closed or opened via the inner cable running in the shaft (a).
Due to the variety of possible anatomical and physiological conditions, myocardial bioptomes differ in their specific characteristics, such as length and design of the shaft or jaw width.

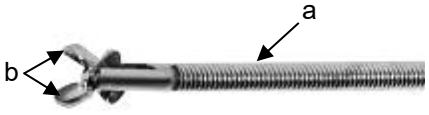

Fig. 1a: Distal working end of the myocardial bioptome, open (highly magnified)

Fig. 1b: Pull roller handle of the myocardial bioptome, proximal end

When the pull-roller handle (c) is relaxed, the jaws are closed (Fig. 2a).
To open the jaws (Fig. 2b) push the ring-shaped handle (d) of the pull-roller handle (c) (Fig. 1b) towards the shaft (a). Press the ring-shaped handle part (d) together to close the jaws (Fig. 2a). The tissue (biopsy specimen) located between the jaws is severed by the sharpened edges, remains within the jaws and can be safely removed from the biopsy site.

Fig. 2a: Closed jaws

Fig. 2b: Open jaw

⚠	Only use flawless and sterilized products!
⚠	Before inserting the myocardial bioptome, ensure that the surgical field has been prepared accordingly.
⚠	Medical devices made of ferromagnetic materials must not be exposed to 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 bioptome depends on the anatomical and physiological conditions as well as the area of application. Care must be taken to ensure that the myocardial bioptome used is the right size and has sufficient stability.

During the application

The procedure is similar to that of a standard cardiac catheterization; endomyocardial biopsies are usually performed as part of a cardiac catheterization in the cardiac catheterization laboratory.

⚠	The procedure must be performed under X-ray control so that the distal end of the instrument can be brought safely to the removal site. - Risk of injury, if this is not observed!

After disinfection and local anesthesia of the puncture site, a sheath is inserted into the vein (right heart biopsy – femoral or jugular vein) or into an artery (left heart biopsy – femoral artery) using the Seldinger technique.
After disinfection and local anesthesia of the puncture site, the technique consists of puncturing the right jugular or femoral vein, into which a Seldinger sheath is placed. The myocardial bioptome is then guided through the vena cava to the level of the right atrium, then passes the tricuspid valve and samples are taken from the interventricular septum.

⚠	Limit pre-bending of the distal shaft part to the 25 - 50 mm distal area! Observe a minimum radius of 12 - 15 mm! To pre-bend the shaft, place it on both thumbs and then use your index fingers to bend the shaft over both thumbs! Do not bend under any circumstances! Risk of immobility → Risk of injury! Never subject the junction between the shaft and scissor joint to bending stress – risk of breakage → Risk of injury! A function test must be carried out after pre-bending.
⚠	Only insert the myocardial bioptome through the vascular system into the ventricle with the spoon closed - i.e. with the grip parts relaxed! → Risk of injury to the vessel walls due to open spoons! Advance the myocardial bioptome slowly, carefully and without using any force into the working channel; do not bend it! → Risk of injury!
⚠	Remove the myocardial bioptome from the working channel immediately after use. After obtaining the sample, be sure to keep the spoons of the myocardial bioptome closed until the myocardial bioptome is removed from the body and the sample can be retrieved. → Risk of embolism if the biopsy specimen is lost!
After the application	
⊘	Do not reprocess or reuse! Single-use device - risk of infection, if reused!
⚠	Dispose of myocardial bioptomes in accordance with the hospital's own regulations for infectious waste!

7) Storage

In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.
Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage).

⌛	Note the expiry date! Do not use products after the specified expiration date and return them to the manufacturer!

8) Required accessories

No accessories are required to use the myocardial bioptome.

9) Obligation to report serious incidents

The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.

Symbols		
If displayed on the medical device, the label of the medical device or the instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meaning:		
Manufacturer	Follow the instructions for use or use electronic follow the electronic instructions for use	Caution
REF Catalog number	LOT Batch designation	SN Serial number
MD Medical device	UDI Unique Device Identifier	STERILE EO Sterilized with ethylene oxide
Do not reuse	Can be used until	Date of manufacture
Store in a dry place	Simple sterile barrier system	Double sterile barrier system
Protect from sunlight	Do not use if the packaging is damaged, and follow the electronic instructions for use	CE 0297 CE marking
CE marking		
Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.		

Contact the manufacturer	
FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 Email: info@fehling-instruments.de www.fehling-instruments.de	CE 0297