Shock wave applicator CSP0200

Cardiac Shockwave Probe

1 Safety and Performance CSP0200

1.1 General description of the product

Shock waves do not replace medically recognized standard procedures, which are known to have a good prognosis for healing success. It must be ensured that shock wave treatment is used only as an additional therapeutic procedure that complements the conventional, recognized standard procedures.
The CSP0200 is a shock wave applicator designed to generate shock waves. It is intended during coronary arterial bypass grafting (CABG) surgery to treat the myocardium by instructed surgeons.

During the surgery, the patient is connected to a heart-lung machine. Once the bypasses have been placed, the heart-lung machine is slowly shut down and the heart begins to beat independently again. During this phase, shock wave therapy is applied.

The CSP0200 is the applicator for DESWT (Direct Epicardial Shockwave Therapy) and the NRG-HeaRT accessory is the power supply and control unit for the CSP0200 applicator.
The CSP0200 applicator generates acoustic pressure waves, so-called shock waves, according to the electrohydraulic principle. For this purpose, two opposite electrodes are supplied with high voltage, which discharge against each other in a liquid medium. An acoustic pressure wave induced by the spark discharge is reflected by a surrounding reflector and propagates through the liquid medium and the sealing membrane to the treatment area. Coupling takes place through saline solution and through sterile ultrasound gel.

1.2 Intended purpose

The CSP0200 shockwave applicator is used to treat the hibernating myocardium during bypass surgery to improve left ventricular ejection fraction (LVEF).

1.3 Indications

The use of Direct Epicardial Shockwave Therapy (DESWT) is intended as an additional therapy for the following indication:

- Patients with postischemic heart failure (ICD 10 code: I25.9), during coronary artery bypass grafting (CABG).

Mandatory action!
Only diseased areas of the heart and its immediate surroundings should be treated. These areas should be defined as best as possible from previous imaging.

Mandatory action!

Shock waves do not replace the medically recognized standard procedures. It must be ensured that shock wave treatment is only used as an additional therapeutic procedure during surgery, supplementing the conventional, recognized standard procedures.

1.4 Contraindications and exclusions

General exclusion criteria of the DESWT:

- Prior significant ventricular arrhythmias (excluding arrhythmias as a result of myocardial infarction).
- Presence of ventricular thrombus
- Malignant heart tumor
- Pregnancy
- Lung must not be in the focus of the shock wave

1.5 Safety instructions

You may only operate this device in accordance with the descriptions in this instructions for use and only use it for the purpose as specified in the intended use. The use of this medical device is restricted exclusively to physicians with specialist training as surgeons. The medical operating room personnel must be trained as surgical assistants or as health care and nursing staff.
Users must be instructed and trained in the use of this device by the manufacturer or already trained personnel. Any use by other users is not permitted. Users must check the proper functionality and condition of the product before each use.

1.6 Characterization of the Patients

The CSP0200 is intended for male and female patients between the ages of 21 and 90 with postischemic heart failure who have impaired left ventricular ejection fraction (LVEF).
If the patient meets the requirements for performing bypass surgery, shock wave therapy can also be applied.

1.6.1 Vulnerable Population

The characterization of the patient applies also for vulnerable population, as elderly and minorities as well as rare diseases if they are capable of undergoing bypass surgery.

1.7 Performance Characteristics

The performance characteristics of the shockwave applicator is the delivery of focused acoustic shock waves with an energy of 7.2 mJ and an energy flux density of 0.35 mJ/mm^2.

1.8 Warnings and precautions for safe use

1.8.1 General safety instructions

The safe operation of the device is only guaranteed if the following points are observed:

Prohibition!
In general, any modification of the device is not permitted unless described in this instructions for use.

Prohibition!
You must not use the device if it has electrical or mechanical defects. This also applies if error messages are displayed.

Mandatory action!
The CSP0200 shockwave applicator and the CIV-Flex Transducer Cover-Package are single-use products and are intended for one therapy!

Mandatory action!
Only use original accessories as specified or supplied by the manufacturer.

Warning!
The CSP0200 shockwave applicator emits increased audible sound pressure levels. Avoid shock wave emission when the shockwave applicator is not coupled.

Mandatory action!
If you want to emit shock wave pulses for testing purposes, hold the shockwave applicator to a sterile infusion bag filled with liquid.

Warning!
The CSP0200 shockwave applicator emits bright flashes of light with infrared and UV components. Eye hazard is minimized when used properly by coupling the shockwave applicator to a sterile surface to protect against direct visual contact when emitting shockwave pulses for testing.

1.8.2 Electromagnetic Compatibility (EMC)

Warning!
Electromagnetic interactions!
During therapy operation, the device emits increased electromagnetic interference radiation. Patients who wear a pacemaker or implantable cardioverter-defibrillator (ICD) must have this device checked after treatment.

Warning!
Electromagnetic interactions!
The device generates shock waves by spark discharge of a high voltage. Use of the CSP0200 shockwave applicator immediately adjacent to other equipment should be avoided as this could result in incorrect operation of the other equipment. If use in the manner described above is nevertheless necessary, the other devices should be observed to make sure that they are operating properly.

Prohibition!

Do not use high-frequency surgical equipment at the same time!

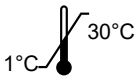
During shock wave application with the CSP0200 shockwave applicator, HF surgical devices such as electrocautery or electroscalpel must not be in operation. This could lead to interference with the NRG-H device.

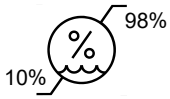
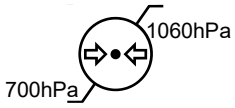
1.9 Residual Risk

The product CSP0200 is designed in such a way that, when used under the intended conditions and for the intended purpose, all risks are acceptable when weighed against the benefits for the patient. The overall residual risk was classified as acceptable. Potential risks associated with the CSP0200 shockwave applicator are the following: Loss or reduction of the therapeutic regeneration effect, burning grade I, damage to the eyes, redness and petechiae, blast trauma, infection, allergic reaction and tissue irritation, tissue lesions, Ventricular fibrillation and death.

1.10 Symbols

Symbols used in documentation, on packaging, labels or on the device:

Symbol	Description
	General warning sign (ISO7010-W001)
	General mandatory action sign (ISO7010-M001)
	General prohibition sign (ISO7010-P001)
	Refer to instruction manual/booklet! (ISO 7010-M002)
	Do not re-use (ISO7000-1051)
	Do not resterilize (ISO7000-2608)
	Non-sterile (ISO7000-2609)
	Temperature limit; a specified temperature range must be observed during storage and transport. (ISO7000-0632)
	Date of manufacture; month and year of manufacture are indicated below the symbol. (ISO 15223-1 5.1.3, ISO7000-2497)
	Use-by date; month and year until which the product may be used are indicated below the symbol. (ISO 15223-1 5.1.4, ISO7000-2607)
	Manufacturer; indicates the manufacturer of the medical device. The name of the manufacturer including the address is indicated next to the symbol. (ISO 15223-1 5.1.1, ISO7000-3082)

Symbol	Description
	Serial number of the manufacturer to identify an individual medical device. The serial number must be placed next to the symbol. (ISO 15223-1 5.1.7, ISO7000-2498)
	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol. (ISO 15223-1 5.1.5 ISO7000-2492)
	Catalogue number of the product (ISO7000-2493)
	Protection class against ingress of water and solid substances. (IEC60529)
	Medical device; Indication that it is a medical device (ISO 15223-1 5.7.7)
	Type CF applied part, for heart application (IEC60417, EN60601-1)
	To identify a foot control device, connection or function. (ISO7000-6378, IEC60417)
	RFID tag; indicates the presence of an RFID identification chip. (ISO7000-3010)
	Humidity limitation; Indication of acceptable upper and lower limits of relative humidity. (ISO 15223-1 5.3.8, ISO7000-2620)
	Atmospheric pressure limitation; Indication of acceptable upper and lower limits of atmospheric pressure. (ISO 15223-1 5.3.9, ISO7000-2621)
	Separate collection of electrical and electronic equipment at disposal. (DIRECTIVE 2012/19/EU - WEEE)
	CE mark with Notified Body number. (EU 2017/745 MDR)

