



Dex Surgical



# DEX Device

## Safety and Performance Information

DEX Surgical  
3 rue des petits ruisseaux  
91370- Verrière-le-BuissonFRANCE  
Tél. (+33) 01.69.20.69.69 – email:  
[contact@dexteritesurgical.com](mailto:contact@dexteritesurgical.com)

## 1. PRESENTATION OF THE DEVICE

The DEX device laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, suturing, transection, and electro-cauterization of tissues.

The DEX Device is an electro-mechanical system designed for surgeon to perform minimal invasive surgeries: laparoscopic surgery. The surgeon will use the system in a similar way than any laparoscopic instruments and remains in contact with the patient.

The specificity the DEX device, like the predicate device, is in its distal articulation that allows the tip (scissors, needle holder, forceps, or Hook) to tilt, rotate and open-close. The surgeon commands these actions by pressing the actuators on the Control handle.

The DEX arms are also compatible with monopolar energy: these are just actives electrodes to be used with an HF generator compliant with IEC 60601-2-2.

*Fig. DEX Device*



The device consists of a Console, a control handle and four Arms instruments; and accessories

### Console and Control handle



*Fig. Console and control handle*

The control unit host the software, designed for product safety and functionally.

## Arms instruments

There are four arms available, all articulated:



*Fig. Arms*

Needle holder Monopolar scissors Monopolar Maryland Monopolar Hook

The Arms can be exchanged manually during the surgery to perform different surgical acts. The scissors, the Maryland, and the hook support electrocautery monopolar energy.

The arms can only be used for a pre-set maximum number of surgical procedures. The arms and the control handle are reusable and autoclavable.

## **2. INTENDED PURPOSE OF THE DEVICE**

### **2.1. INTENDED USE**

The DEX device laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, suturing, transection, and electro-cauterization of tissues.

### **2.2. TARGET POPULATION**

All patients: Men, women and children that need to have a surgery of the soft tissue with the use of minimally invasive/ laparoscopic technique.

### **2.3. INTENDED USER**

DEX device is reserved to be use in hospitals by minimal invasive/ laparoscopic surgeons.

### **2.4. INDICATIONS**

For surgery of the soft tissue with the use of minimally invasive/laparoscopic technique in the indications of ambulatory surgery, gynecology surgery, cardiac, thoracic surgery, pediatric surgery, vascular surgery, visceral and digestive surgery; urology, ENT.

### **2.5. CONTRAINDICATIONS**

The contraindications related to the use of DEX device are the contraindications of the minimally invasive/laparoscopic surgery technique.

In case of use in conjunction with ESU for monopolar energy, please refer to the ESU IFU for contraindications.

### **2.6. POTENTIAL COMPLICATIONS**

No potential complications are identified.

### **2.7. CLINICAL CLAIMS**

The purpose of the DEX Device manufactured by DEX Surgical is to be used in addition with regular instrument during laparoscopic surgery. The DEX Device will be used when movements with straight instruments (regular) become too complicated or to overcome an anatomical complex situation: narrow spaces, posterior access.

The clinical performances of those DEX Device result strictly from its technical characteristics to correctly act to reach the claimed clinical benefit.

The technical parameters of the performances of the device that will be used to assess the clinical benefit are as following:

*For the Console/handle set for minimally invasive surgery*

Control of the distal mobility:

- Rotation of the motors responding to a command of the Handle to rotate the tip of an arm.
- Rotation of the motors responding to a command of the Handle to open/close the tip of an arm.
- Rotation of the motors responding to a command of the Handle to tilt the tip of an arm.

Ergonomic prehension: Improved postural comfort of the surgeon during laparoscopic surgery with the help of the articulation of the control handle and the actuation of the tip by motors: rotation of the Handle to improve the postural comfort.

*For the Articulated arm for minimally invasive surgery*

Distal mobility (will also improve postural comfort)

Rotation of the tip responding to a command of the Handle.

Open/close of the tip responding to a command of the Handle.

Tilt of the tip responding to a command of the Handle.

## **2.8. CLINICAL BENEFIT**

The use of this DEX Device manufactured by DEX SURGICAL allows the surgeon to ease the way to perform suturing, dissection, tissue manipulation during minimally invasive/laparoscopic surgery.

Especially when the surgeon must perform suturing, dissection, tissue manipulation, tissue coagulation when used in conjunction with standard ESU.

Therefore, the clinical benefit brought by the DEX Device results of an indirect clinical effect. This indirect clinical effect is based on clinical performances relating essentially to technical characteristics of the device.