Dex Surgical



DEX Device

Product Name
Safety and Performance Information

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Safety and performance document.Rev2
Date: 08/10/2025

1. PRODUCT NAME TRANSLATION

Référence	BG	CS	DA	DE	EL	EN	ES	FI	FR	IT	LT
B-1301C20N	Държач за игли ръка F	Držák jehly rameno F	Nålholder arm F	Nadelhalter Arm F	Κρατητήρας βελόνας βραχίονα F	Arm needle holder F	Porta-agujas brazo F	Neulanpidin varsi F	Porte-aiguille bras F	Porta-aghi braccio F	Adatai laikiklis ranka F
B-1301C40N	Държач за игли ръка	Držák jehly rameno	Nålholder arm	Nadelhalter Arm	Κρατητήρας βελόνας βραχίονα	Arm needle holder	Porta-agujas brazo	Neulanpidin varsi	Porte-aiguille bras	Porta-aghi braccio	Adatai laikiklis ranka
B-1301D20N	Държач за игли ръка демо	Držák jehly rameno demo	Nålholder arm demo	Nadelhalter Arm demo	Κρατητήρας βελόνας βραχίονα demo	Arm needle holder demo	Porta-agujas brazo demo	Neulanpidin varsi demo	Porte-aiguille bras démo	Porta-aghi braccio demo	Adatai laikiklis ranka demo
B-1301C40L	Държач за игли ръка дълъг	Držák jehly rameno dlouhý	Nålholder arm lang	Langer Nadelhalter Arm	Μακρύς κρατητήρας βελόνας βραχίονα	Arm needle holder long	Porta-agujas brazo largo	Pitkä neulanpidin varsi	Porte-aiguille bras long	Porta-aghi braccio lungo	Ilgas adatai laikiklis ranka
B-1301C40S	Държач за игли ръка къс	Držák jehly rameno krátký	Nålholder arm kort	Kurzer Nadelhalter Arm	Κοντός κρατητήρας βελόνας βραχίονα	Arm needle holder short	Porta-agujas brazo corto	Lyhyt neulanpidin varsi	Porte-aiguille bras court	Porta-aghi braccio corto	Trumpas adatai laikiklis ranka
B-1304C10N	Ръчна монополярна ножица F	Rameno monopolární nůžky F	Monopolær saks arm F	Monopolare Schere Arm F	Μονοπολικός ψαλίδι βραχίονα F	Arm Monopolar Scissors F	Tijeras monopolares brazo F	Monopolaariset sakset varsi F	Ciseaux monopolaire bras F	Forbici monopolari braccio F	Monopolinės žirklės ranka F
B-1304C20N	Ръчна монополярна ножица	Rameno monopolární nůžky	Monopolær saks arm	Monopolare Schere Arm	Μονοπολικός ψαλίδι βραχίονα	Arm Monopolar Scissors	Tijeras monopolares brazo	Monopolaariset sakset varsi	Ciseaux monopolaire bras	Forbici monopolari braccio	Monopolinės žirklės ranka
B-1304D10N	Ръчна монополярна ножица демо	Rameno monopolární nůžky demo	Monopolær saks arm demo	Monopolare Schere Arm demo	Μονοπολικός ψαλίδι βραχίονα demo	Arm Monopolar Scissors demo	Tijeras monopolares brazo demo	Monopolaariset sakset varsi demo	Ciseaux monopolaire bras démo	Forbici monopolari braccio demo	Monopolinės žirklės ranka demo
B-1304C20L	Ръчна монополярна ножица дълга	Rameno monopolární nůžky dlouhé	Monopolær saks arm lang	Lange monopolare Schere Arm	Μακριά μονοπολικός ψαλίδι βραχίονα	Arm Monopolar Scissors long	Tijeras monopolares brazo largas	Pitkät monopolaariset sakset varsi	Ciseaux monopolaire bras long	Forbici monopolari braccio lunghe	Ilgos monopolinės žirklės ranka
B-1304C20S	Ръчна монополярна ножица къса	Rameno monopolární nůžky krátké	Monopolær saks arm kort	Kurze monopolare Schere Arm	Κοντό μονοπολικός ψαλίδι βραχίονα	Arm Monopolar Scissors short	Tijeras monopolares brazo cortas	Lyhyet monopolaariset sakset varsi	Ciseaux monopolaire bras court	Forbici monopolari braccio corte	Trumpos monopolinės žirklės ranka
B-1505C20N	Дисектор Мериленд F	Maryland disektor rameno F	Maryland arm F	Maryland Arm F	Διαχωριστής Maryland βραχίονα F	Arm Maryland F	Disector Maryland brazo F	Maryland dissektori varsi F	Dissecteur Maryland bras F	Dissettore Maryland braccio F	Maryland disektorius ranka F
B-1505C40N	Дисектор Мериленд	Maryland disektor rameno	Maryland arm	Maryland Arm	Διαχωριστής Maryland βραχίονα	Arm Maryland	Disector Maryland brazo	Maryland dissektori varsi	Dissecteur Maryland bras	Dissettore Maryland braccio	Maryland disektorius ranka
B-1505D20N	Дисектор Мериленд демо	Maryland disektor rameno demo	Maryland arm demo	Maryland Arm demo	Διαχωριστής Maryland βραχίονα demo	Arm Maryland demo	Disector Maryland brazo demo	Maryland dissektori varsi demo	Dissecteur Maryland bras démo	Dissettore Maryland braccio demo	Maryland disektorius ranka demo
B-1505C40L	Дисектор Мериленд дълъг	Maryland disektor rameno dlouhý	Maryland arm lang	Langer Maryland Arm	Μακρύς διαχωριστής Maryland βραχίονα	Arm Maryland long	Disector Maryland brazo largo	Pitkä Maryland dissektori varsi	Dissecteur Maryland bras long	Dissettore Maryland braccio lungo	Ilgas Maryland disektorius ranka
B-1505C40S	Дисектор Мериленд къс	Maryland disektor rameno krátký	Maryland arm kort	Kurzer Maryland Arm	Κοντός διαχωριστής Maryland βραχίονα	Arm Maryland short	Disector Maryland brazo corto	Lyhyt Maryland dissektori varsi	Dissecteur Maryland bras court	Dissettore Maryland braccio corto	Trumpas Maryland disektorius ranka
B-1506C40N	Кука ръка F	Háček rameno F	Krog arm F	Haken Arm F	Γάντζος βραχίονα F	Arm Hook F	Gancho brazo F	Koukku varsi F	Crochet bras F	Gancio braccio F	Kablys ranka F
B-1506C60N	Кука ръка	Háček rameno	Krog arm	Haken Arm	Γάντζος βραχίονα	Arm Hook	Gancho brazo	Koukku varsi	Crochet bras	Gancio braccio	Kablys ranka
B-1506D20N	Кука ръка демо	Háček rameno demo	Krog arm demo	Haken Arm demo	Γάντζος βραχίονα demo	Arm Hook demo	Gancho brazo demo	Koukku varsi demo	Crochet bras démo	Gancio braccio demo	Kablys ranka demo
B-1506C60L	Кука ръка дълга	Háček rameno dlouhý	Krog arm lang	Langer Haken Arm	Μακρύς γάντζος βραχίονα	Arm Hook long	Gancho brazo largo	Pitkä koukku varsi	Crochet bras long	Gancio braccio lungo	Ilgas kablys ranka
B-1506C60S	Кука ръка къс	Háček rameno krátký	Krog arm kort	Kurzer Haken Arm	Κοντός γάντζος βραχίονα	Arm Hook short	Gancho brazo corto	Lyhyt koukku varsi	Crochet bras court	Gancio braccio corto	Trumpas kablys ranka
EP-1301	Конзола и дръжка дясна	Konzola a rukoješť pravá	Konsol og håndtag højre	Konsole und Griff rechts	Κονσόλα και λαβή δεξιά	Console and handle right	Consola y mango derecho	Konsoli ja kahva oikea	Console et poignée droite	Console e maniglia destra	Konsolė ir dešinė rankena
EP-1302	Конзола и дръжка лява	Konzola a rukoješť levá	Konsol og håndtag venstre	Konsole und Griff links	Κονσόλα και λαβή αριστερά	Console and handle left	Consola y mango izquierdo	Konsoli ja kahva vasen	Console et poignée gauche	Console e maniglia sinistra	Konsolė ir kairė rankena
M-1304	Моно полярный чехол	Monopolární návlek	Monopolær hylster	Monopolare Hülle	Μονοπολική θήκη	Monopolar sleeve	Funda monopolar	Monopolaari holkki	Manchon monopolaire	Guaina monopolare	Monopolinis apvalkalas
2090-MDS	Защитный чехол	Ochranný návlek	Beskyttelseshylster	Schutzhülle	Θήκη προστασίας	Protection sleeve	Funda protectora	Suoja holkki	Manchon de protection	Guaina di protezione	Apsauginis apvalkalas

Référence	LV	NL	PL	PT	RO	RU	SL	SV	TR	UK
B-1301C20N	Adatu turētājs roka F	Naaldhouder arm F	Uchwyt igły ramię F	Porta-agulha braço F	Portacui braț F	Иглодержатель рука F	Držalo igle roka F	Nålhållare arm F	İğne tutucu kol F	Тримач голки рука F
B-1301C40N	Adatu turētājs roka	Naaldhouder arm	Uchwyt igły ramię	Porta-agulha braço	Portacui braț	Иглодержатель рука	Držalo igle roka	Nålhållare arm	İğne tutucu kol	Тримач голки рука
B-1301D20N	Adatu turētājs roka demo	Naaldhouder arm demo	Uchwyt igły ramię demo	Porta-agulha braço demo	Portacui braț demo	Иглодержатель рука демо	Držalo igle roka demo	Nålhållare arm demo	İğne tutucu kol demo	Тримач голки рука демо
B-1301C40L	Garš adatu turētājs roka	Lange naaldhouder arm	Długi uchwyt igły ramię	Porta-agulha braço longo	Portacui braț lung	Длинный иглодержатель рука	Dolgo držalo igle roka	Lång nålhållare arm	Uzun iğne tutucu kol	Довгий тримач голки рука
B-1301C40S	Īss adatu turētājs roka	Korte naaldhouder arm	Krótki uchwyt igły ramię	Porta-agulha braço curto	Portacui braț scurt	Короткий иглодержатель рука	Kratko držalo igle roka	Kort nålhållare arm	Kısa iğne tutucu kol	Короткий тримач голки рука
B-1304C10N	Monopolāras šķēres roka F	Monopolaire schaar arm F	Nożyczki monopolowe ramię F	Tesoura monopolar braço F	Foarfeca monopolară braț F	Монополярные ножницы рука F	Monopolne škarje roka F	Monopolär sax arm F	Monopolar makas kol F	Монополярні ножиці рука F
B-1304C20N	Monopolāras šķēres roka	Monopolaire schaar arm	Nożyczki monopolowe ramię	Tesoura monopolar braço	Foarfeca monopolară braț	Монополярные ножницы рука	Monopolne škarje roka	Monopolär sax arm	Monopolar makas kol	Монополярні ножиці рука
B-1304D10N	Monopolāras šķēres roka demo	Monopolaire schaar arm demo	Nożyczki monopolowe ramię demo	Tesoura monopolar braço demo	Foarfeca monopolară braț demo	Монополярные ножницы рука демо	Monopolne škarje roka demo	Monopolär sax arm demo	Monopolar makas kol demo	Монополярні ножиці рука демо
B-1304C20L	Garu monopolāras šķēres roka	Lange monopolaire schaar arm	Długie nożyczki monopolowe ramię	Tesoura monopolar braço longa	Foarfeca monopolara braț lungă	Длинные монополярные ножницы рука	Dolge monopolne škarje roka	Långa monopolär sax arm	Uzun monopolar makas kol	Довгі монополярні ножиці рука
B-1304C20S	Īsās monopolāras šķēres roka	Korte monopolaire schaar arm	Krótkie nożyczki monopolowe ramię	Tesoura monopolar braço curta	Foarfeca monopolara braț scurtă	Короткие монополярные ножницы рука	Kratke monopolne škarje roka	Korta monopolär sax arm	Kısa monopolar makas kol	Короткі монополярні ножиці рука
B-1505C20N	Maryland dissektors roka F	Maryland dissector arm F	Dyssektor Maryland ramię F	Dissector Maryland braço F	Dissector Maryland braț F	Мэриленд диссектор рука F	Maryland disektor roka F	Maryland dissektor arm F	Maryland kol F	Меріленд рука F
B-1505C40N	Maryland dissektors roka	Maryland dissector arm	Dyssektor Maryland ramię	Dissector Maryland braço	Dissector Maryland braț	Мэриленд диссектор рука	Maryland disektor roka	Maryland dissektor arm	Maryland kol	Меріленд рука
B-1505D20N	Maryland dissektors roka demo	Maryland dissector arm demo	Dyssektor Maryland ramię demo	Dissector Maryland braço demo	Dissector Maryland braț demo	Мэриленд диссектор рука демо	Maryland disektor roka demo	Maryland dissektor arm demo	Maryland kol demo	Меріленд рука демо
B-1505C40L	Garš Maryland dissektors roka	Maryland dissector arm lang	Długi dyssektor Maryland ramię	Dissector Maryland braço longo	Dissecteur Maryland braț lung	Длинный Мэриленд рука	Dolg Maryland roka	Lång Maryland arm	Uzun Maryland kol	Довгий Меріленд рука
B-1505C40S	Īss Maryland dissektors roka	Maryland dissector arm short	Krótki dyssektor Maryland ramię	Dissector Maryland braço curto	Dissecteur Maryland braț scurt	Короткий Мэриленд рука	Kratek Maryland roka	Kort Maryland arm	Kısa Maryland kol	Короткий Меріленд рука
B-1506C40N	Āķis roka F	Haak arm F	Hak ramię F	Gancho braço F	Cârlig braț F	Крючок рука F	Kavelj roka F	Krok arm F	Kanca kol F	Гачок рука F
B-1506C60N	Āķis roka	Haak arm	Hak ramię	Gancho braço	Cârlig braț	Крючок рука	Kavelj roka	Krok arm	Kanca kol	Гачок рука
B-1506D20N	Āķis roka demo	Haak arm demo	Hak ramię demo	Gancho braço demo	Cârlig braț demo	Крючок рука демо	Kavelj roka demo	Krok arm demo	Kanca kol demo	Гачок рука демо
B-1506C60L	Garš āķis roka	Lange haak arm	Długi hak ramię	Gancho braço longo	Cârlig braț lung	Длинный крючок рука	Dolg kavelj roka	Lång krok arm	Uzun kanca kol	Довгий гачок рука
B-1506C60S	Īss āķis roka	Korte haak arm	Krótki hak ramię	Gancho braço curto	Cârlig braț scurt	Короткий крючок рука	Kratek kavelj roka	Kort krok arm	Kısa kanca kol	Короткий гачок рука
EP-1301	Konsoles un labā roka	Console en handgreep rechts	Konsola i uchwyt prawy	Console e punho direito	Consolă și mâner drept	Консоль и рукоятка правая	Konzola in ročaj desno	Konsol och handtag höger	Konsol ve sağ tutamak	Консоль і ручка права
EP-1302	Konsoles un kreisā roka	Console en handgreep links	Konsola i uchwyt lewy	Console e punho esquerdo	Consolă și mâner stâng	Консоль и рукоятка левая	Konzola in ročaj levo	Konsol och handtag vänster	Konsol ve sol tutamak	Консоль і ручка ліва
M-1304	Monopola vāks	Monopolaire hoes	Rękaw monopolar	Bainha monopolar	Manșon monopolara	Монополярный чехол	Monopolarna tulejka	Monopolär hylsa	Monopolar kılıf	Монополярний чохол
2090-MDS	Aizsargvāks	Beschermhoes	Osłona ochronna	Bainha de proteção	Manșon de protecție	Защитный чехол	Zaščitna tulejka	Skyddshylsa	Koruyucu kılıf	Захисний чохол

2. 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.

3. INTENDED PURPOSE OF THE DEVICE

3.1. 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.

3.2. 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.

3.3. INTENDED USER

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

3.4. 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, visceraland digestive surgery; urology, ENT.

3.5. CONTRAINDICATIONS

The contraindications related to the use of DEX device are the contraindications of the minimally invasive/laparoscopic surgery technique.
In case of use is use in conjunction with ESU for monopolar energy, please refer to the ESU IFU for contraindications.

3.6. POTENTIAL COMPLICATIONS

No potential complications are identified.

3.7. 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 thepostural 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.

3.8. CLINICAL BENEFIT

The use of this DEX Device manufactured by DEX SURGICAL allows the surgeon to Ease the way to performsuturing, dissection, tissue manipulation during minimally invasive/laparoscopic surgery.
Especially when the surgeon must perform suturing, dissection, tissue manipulation, tissue coagulation when usein conjunction with standard ESU.

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