

Instructions for Use (IFU) Dexter® Addendum

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1 INTRODUCTION

This addendum to the Dexter L6 System Instructions for Use provides supplementary information regarding the use of the Emergency Release Tool (REF 145) instead of the Emergency Release Tool (REF 487), as described in the Instructions for Use (ID: EDU-IFU-MDD-v1_5_4).

The main differences between the Emergency Release Tool (REF 145) and the Emergency Release Tool (REF 487) are highlighted in the table below.

CHANGE	EMERGENCY RELEASE TOOL (REF 145)	EMERGENCY RELEASE TOOL (REF 487)
Material	Stainless steel shaft and a nylon handle	Single piece of stainless steel
Number of uses (including reprocessing)	Up to 100 uses	Can be used as long as the visual inspection criteria are met
Label	No UDI	UDI engraved on handle

This supplement is necessary until the Emergency Release Tool (REF 487) becomes available. It is recommended to keep this addendum with your Dexter L6 System Instructions for Use.

This addendum provides updated information for the following sections of the Instructions for Use:

- Section 2.1 Device Overview
- Section 2.6 Reusable Accessories
- Section 15 Accessories Reprocessing
- Section 16.2.1 Compliance and Classifications
- Section 16.2.3 Key Physical Characteristics
- Section 16.4.1 Service Life
- Section 20.1.1 General Terms



1.1 GENERAL INFORMATION

Use the following information for customer service, including ordering, reporting complaints or adverse events, general information regarding Distalmotion or our products and services.

In addition, use the following information if the Dexter L6 System requires maintenance or service. Preventive maintenance is required and must be performed by authorized Distalmotion personnel. There are no user-serviceable parts.



Address: Distalmotion SA | Route de la Corniche 3b | 1066 Epalinges | Switzerland

Phone: +41 21 510 58 91

Email: support@distalmotion.com

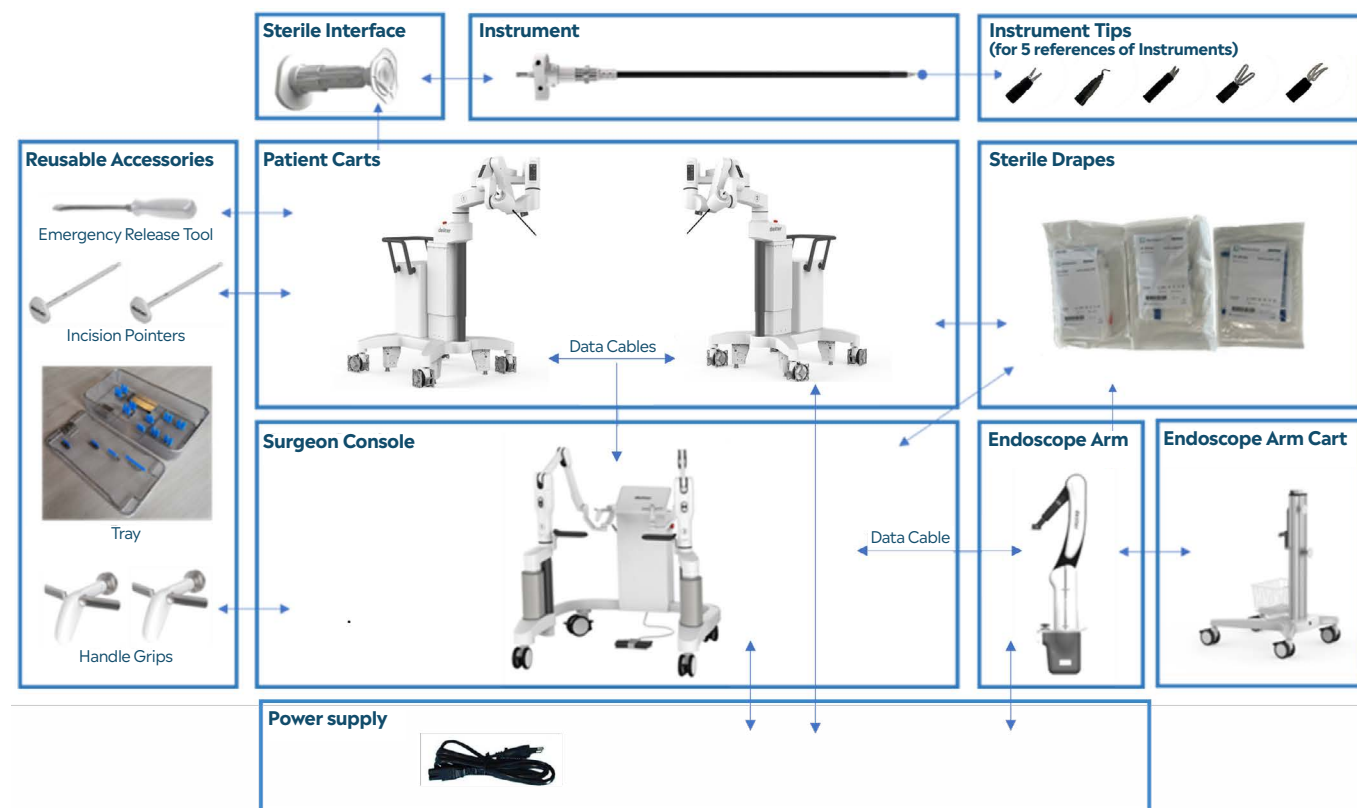
1.2 SYMBOLS

The following symbol and definition are used throughout this document:

SYMBOL	DEFINITION
	Warning: Warning messages alert the reader about a potentially hazardous situation which, if not avoided, may result in injury to the user or patient, or damage to the equipment or other property. Warning messages may also be used to alert against unsafe practices. Warning messages may include information about any special care necessary for the safe and effective use of the device, and any care necessary to avoid damage to the device that may occur as a result of use or misuse.

2 UPDATED INFORMATION

Section 2.1: Device Overview

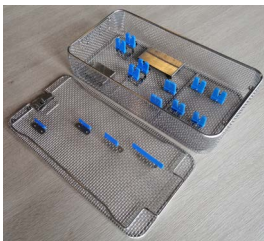




Section 2.6: Reusable Accessories

Dexter L6 System reusable accessories include the Accessory Tray, Incision Pointers for docking the Patient Carts to the patient, the Handle Grips which connect to the Handles of the Surgeon Console, and the Emergency Release Tool for the removal of instruments from the Patient Carts in case of power loss or system failure.

Dexter L6 System reusable accessories are not provided sterile and are reprocessed using standard washer-disinfector and steam sterilization methods.

ACCESSORY TRAY	HANDLE GRIP	INCISION POINTER	EMERGENCY RELEASE TOOL
AC-RU-T (REF 147)	AC-RU-HG (REF 146)	AC-RU-IP (REF 413)	AC-RU-ERT (REF 145)
			
1x	2x	2x	1x
To transport, store and reprocess the Handle Grips, the Incision Pointers and the Emergency Release Tool.	Connected to the Surgeon Console. Held by the surgeon to control the Dexter L6 System.	To dock the Patient Carts to the trocars.	To open instrument blades when Dexter L6 System stops working and instruments grab tissue.

Section 15: Accessories Reprocessing



Do not use washer-disinfectors that are not compliant with ISO 15883.



Enclose the Accessory Tray with standard sterilization wrap according to manufacturer's instructions.



The Handle Grips, Incision Pointers and Emergency Release Tool should only be reprocessed by using the dedicated Accessory Tray and by respecting the designated location for each accessory. No other accessories, aside from those specified, should be reprocessed using the Accessory Tray.



The accessories should be handled and operated by trained personnel. Handle with care. Avoid any mechanical shocks or stress that can cause damage to the device!

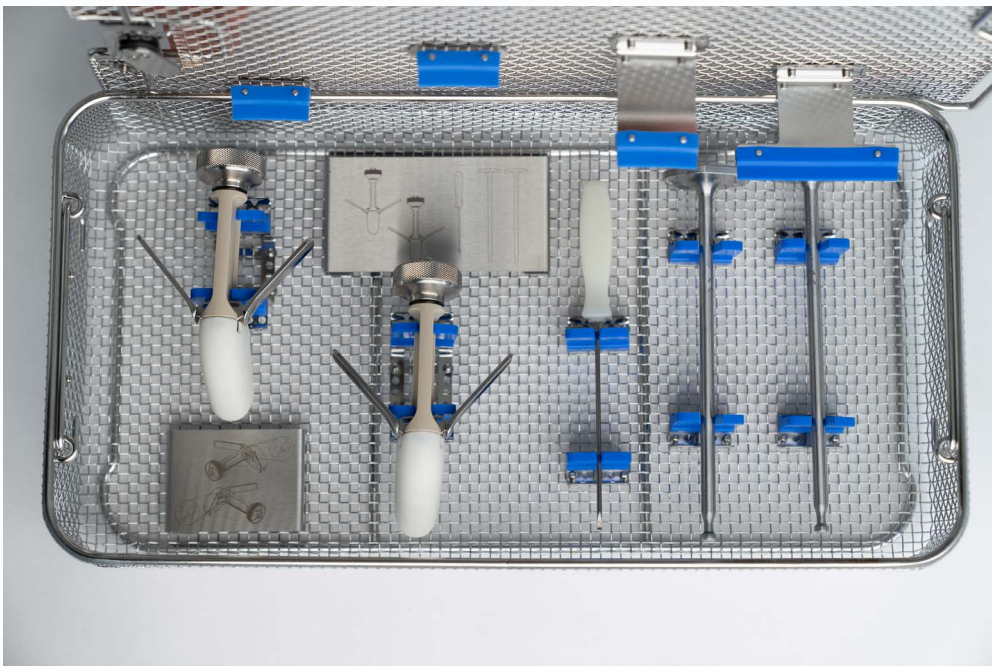


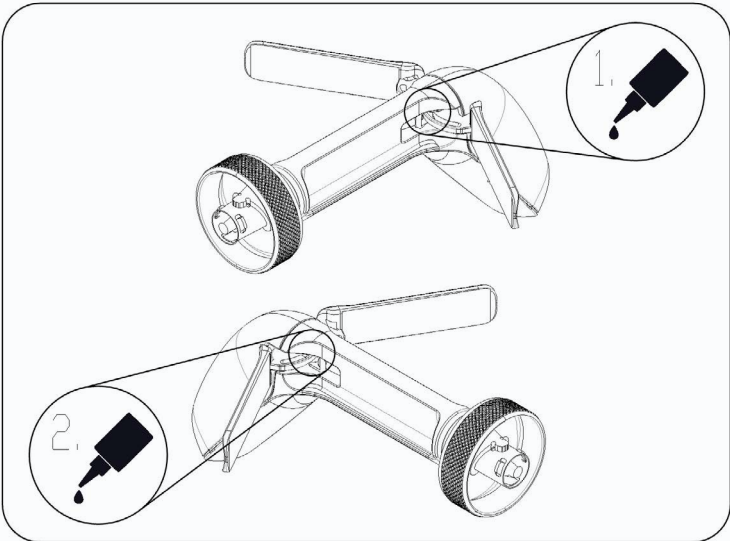
The reprocessing of the reusable accessories must start within 60 minutes after the procedure. It is recommended that the accessories are reprocessed as soon as possible after use. Do not allow blood or residual tissue to dry on the accessories.



The instructions have been validated by Distalmotion as being capable of preparing the reusable accessories of the Dexter L6 System for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

**Section 15.1: Detailed Instructions**

STEP	INSTRUCTIONS
Initial treatment at the point of use:	Remove contamination: Wipe or rinse with water to remove visible blood or other bodily liquids/substances. Prepare for transportation: Place the Handle Grips with open paddles, the Incision Pointers and the Emergency Release Tool at the appropriate place in the Accessory Tray according to the drawing on the top metallic plate, and close the Accessory Tray. 
Preparation before cleaning:	No preparation such as disassembly, gross debris removal or testing procedures is required prior to cleaning.
Cleaning:	Automated cleaning: With a washer-disinfector meeting the requirements of the ISO 15883 series, using enzymatic solution, and followed by rinsing with water. Suitable cleaning agents are: • MediClean Forte from Dr. Weigert • Prozyme Alka-x from Borer Chemie
Disinfection:	No additional disinfection required.
Drying:	Handle Grips: To speed-up reprocessing, the handle grips may be dried using pressurized air.

STEP	INSTRUCTIONS
Visual Inspection:	The following criteria should be taken into account while inspecting the accessories listed below: ● Incision Pointer: Verify there is no deformation or surface alteration (corrosion, stains, degraded marking). ● Tray: Verify there is no deformation or surface alteration (corrosion, stains, degraded marking). ● Handle Grip: Verify there is no deformation, damaged part, surface alteration (corrosion on metal part or degraded marking). Color modification of the plastic part is an expected aging reaction of the polymer and is therefore acceptable. This accessory is limited to 300 sterilization cycles. ● Emergency Release Tool: Verify there is no deformation, damaged part, surface alteration (corrosion on metal part, cracks on plastic part or degraded marking). Color modification of the plastic part is an expected aging reaction of the polymer and is therefore acceptable. This accessory is limited to 100 sterilization cycles. If the criteria above are not met, the accessory should be discarded following the related instructions in Disposal Information section.
Lubrication:	Lubricate the Handle Grip actuation mechanism with a silicone-free, steam permeable and pH-neutral lubrication product (for example, instrument care oil or an equivalent lubricant intended for surgical instruments that are sterilized). Place one drop on each side of the mechanism:  No lubrication required for the other accessories.
Packaging:	Wrapping: The accessory tray is packaged with sterilization wrap.
Sterilization:	Moist heat: Steam sterilization of at least 134° C for at least 3 minutes and up to 18 minutes, following respective national guidance documents on sterilization.
Storage:	No special storage requirements.
Additional information:	No additional information.



STEP	INSTRUCTIONS
Manufacturer contact:	Distalmotion SA  Route de la Corniche 3b 1066 Epalinges Switzerland  reprocessing@distalmotion.com  www.distalmotion.com/

Section 16.2.1 Compliance and Classifications

ITEM NAME	ITEM ID	ARTICLE (REF)	EMDN	CLASSIFICATION (MDR)	TYPE OF USE
Dexter L6 Handle Grip	AC-RU-HG	146	Z120201	Class I (rule 1)	Reusable
Dexter L6 Incision Pointer	AC-RU-IP	413	Z120201	Class I (rule 1)	Reusable
Dexter L6 Emergency Release Tool	AC-RU-ERT	145	Z120201	Class I (rule 1)	Reusable
Dexter L6 Accessory Tray	AC-RU-T	147	S010401	Class I (rule 1)	Reusable
Dexter L6 Endoscope Cart	DM-L6-EC	339	Z120290	Class I (rules 1)	Reusable

Section 16.2.3 Key Physical Characteristics

ITEM	SIZE	WEIGHT	POWER SUPPLY
Surgeon Console	1090 x 1035 x 1200 mm	86 kg	350 VA, 100-240V~, 50/60Hz
Patient Cart	1425 x 850 x 815 mm	230 kg	700 VA, 100-240V~, 50/60Hz
Endoscope Cart	700 x 600 x 1300 mm	32 kg	n/a
Needle Holder	575 x 63 x 45 mm	99 g	n/a
Johann Grasper	611 x 63 x 45 mm	107 g	≤770 Vp
Bipolar Maryland	610 x 63 x 45 mm	106 g	≤770 Vp
Monopolar Scissors	604 x 63 x 45 mm	105 g	≤4 kVpeak
Monopolar Hook	606 x 63 x 45 mm	99 g	≤4 kVpeak
Sterile interface	ø74 x 134 mm	35 g	n/a
Surgeon Console Master Arm Drapes	2350 x 1400 x 0.4 mm	150 g	n/a
Surgeon Console Central Pillar drape	905 x 700 x 0.4 mm	80 g	n/a
Patient Cart Drape	3300 x 1300 x 0.6 mm	220 g	n/a
Accessories Tray	480 x 250 x 110 mm	2.25 kg	n/a

ITEM	SIZE	WEIGHT	POWER SUPPLY
Handle Grip	140 x 120 x 80 mm	224 g	n/a
Incision Pointer	ø50 x 207 mm	165 g	n/a
Emergency Release Tool	183 x 18 x 18 mm	30 g	n/a
Endoscope Arm	291 x 167 x 1059 mm	11.5 kg	100-240 V

Section 16.4.1 Service Life

The expected service life is defined as follows:

Surgeon Console & Patient Carts	Expected service life of 7 years or up to 2912 surgeries.
Endoscope Arm	Expected service life of 10 years or up to 3000 surgeries.
Instruments	Shelf-life of 18 months. Single-use (do not reuse).
Sterile Interfaces	Shelf-life of 36 months. Single-use (do not reuse).
Sterile Drapes	Shelf-life of 5 years. Single-use (do not reuse).
Accessory Tray	Can be used as long as the visual inspection criteria of the accessories reprocessing instructions are met. To cover the service life of the system, this accessory needs to be replaced by a new one.
Handle Grips	Can be use for up to 300 uses. To cover the service life of the system, this accessory needs to be replaced by a new one.
Incision Pointers	Can be used as long as the visual inspection criteria of the accessories reprocessing instructions are met. To cover the service life of the system, this accessory needs to be replaced by a new one.
Emergency Release Tool	Can be use for up to 100 uses. To cover the service life of the system, this accessory needs to be replaced by a new one.

Section 20.1 General Terms

Emergency Release Tool

Used to open instrument blades in the event that the Dexter L6 System stops working and the instruments grab tissue or hold a needle or suture (Manual Emergency Instrument Release).





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