REUSABLE LAPAROSCOPIC INSTRUMENTS

Ackermann©

IMPORTANT
Before using these products, please read the following information thoroughly!

WARNING

Reusable Ackermann products are delivered unsterile, indicated on the device label by the following symbol:

NON STERILE

Prior to their first use, the devices need to be cleaned and sterilized as described in the reprocessing section of this document.

INTENDED USE

The Ackermann Monopolar, Detachable Laparoscopic Instruments are intended to be used as active electrosurgical devices where monopolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.

CONTRAINDICATIONS

The Ackermann Monopolar, Detachable Laparoscopic Instruments are not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

CONTRAINDICATIONS TO ENDOSCOPIC PROCEDURES, NOT NECESSARILY MONOPLOAR COAGULATION INCLUDE

As identified in the Manual of Endoscopy available from the American Association of Gynecologic Laparoscopists. The presence of large pelvic or pelvic-abdominal masses, hypovolemic shock and severe cardiac decompensation. Also, intestinal obstruction and marked bowel distention, increase possibility of pelvic and abdominal adhesions.
A significantly elevated diaphragm contra-indicates the use of insufflation which may be necessary for proper surgical visualisation and may increase the chance of inadvertent bowel injury.
Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.
Caution: Please refer to the labelling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

GENERAL SAFETY PRECAUTION

Improper use of electro surgical equipment and accessories may pose a significant health risk to the patient, user or third party.
Strict adherence to the intended use and safety precautions as well as a thorough understanding of biophysical principles of electro surgery is essential for the safe use of the devices! In this regard, the following safety measures shall always be taken into account:

►Always select the lowest possible power setting that provides the desired effect
►Use brief intermittent activation
►Do not activate in close proximity or direct contact with other instruments especially if they are made of metallic materials
►In order to minimize the chances of direct trauma; activate the electrode only when whole tissue is in the field of vision
►Do not activate in open circuit
►Choose the proper current waveform mode. In monopolar electrosurgery, either the cutting or coagulation waveform can be used to achieve a cutting effect or fulguration effect
►If available, use electrosurgical accessory safety equipment, such as active or return ground electrode monitoring systems when possible

DEVICE SPECIFIC WARNINGS AND PRECAUTIONS

The devices are indicated for a maximum power output of 450Watts / 2.000 Vpeak. Exceeding the indicated maximum power output may result in serious burns and life-threatening injuries to the patient.
It is important to ensure that all active accessory and devices used in combination, such as neutral electrodes, high frequency cables and generators are suitable in terms of their respective dielectric strength.
Extreme care should be taken when handling instruments with insulation. Damage to the insulation may result in patient/user injury.
Prior to every use of the devices, the active insulation should be inspected carefully in regard to damages or inhomogeneity.
Do not try to modify the instrument. Do not try to repair the electrical insulation.
Do not place the instrument on the patient when not in use. Place the instrument in an insulated support or on a clean, dry, visible and non-conductive surface in order to avoid accidental electrical injuries.
After use, the temperature of the active electrode can remain high enough to cause burns to the patient user or third party, even when the electrical current is turned off.
Activating the electrode in the air when not in use will create an "open" circuit, which can also result in a capacitive coupling effect. Capacitive coupling is increased by open circuits, use of 5-mm cannulas (versus 10 mm), and higher generator voltages. This situation can be avoided by using brief intermittent activation that allows normal tissue to remain cool.

RISKS RELATED TO THE APPLICATION

►Thermal damage may cause carbonization at the excision margin, vessel thrombosis, and collagen denaturation. Therefore careful consideration regarding the advantages and suitability of the intended application is recommended.
►Low frequency current my cause electrolysis at the interface between active electrode and tissue. Chemical effects of electrolysis disappear at higher frequencies
►A direct or low frequency current can depolarize cell membranes and cause neuromuscular excitation.
►If the active electrode cable comes in close proximity to the patient's body, current leakage may result in a burn
►Bowel preparation is important if it is anticipated that the large bowel is at risk
►The chances of direct trauma are increased during laparoscopic surgery because surgeons are limited to visualization in only two dimensions, with their hands generally dissociated from their eyes, especially when operating on mobile organs. In order to minimize the chances of direct trauma; activate the electrode only when whole tissue is in the field of vision.
►Do not use electrosurgical instruments on patients with pacemakers.
►Do not use in presence of flammable liquids or anaesthetics.

RISKS RELATED TO INTERFERENCE WITH HF-ACCESSORY AND OTHER COMBINATION DEVICES

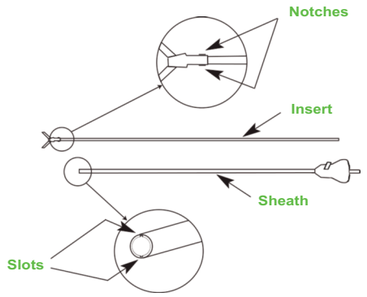
►Avoid hybrid trocar sleeves. The use of non-metal trocar cannulas can reduce the risk of capacitive coupling.
►Apply the patient return electrode according to the recommendations of the generator manufacturer.
►The entire surface of the neutral electrode should be securely connected to the patient's body and as close as possible to the surgical field.
►The patient should not be in contact with grounded metal parts or parts having an appreciable capacity with respect to the ground (for example operating table, supports, etc.). Antistatic wrapping is recommended in this case.
►Skin to skin contact (for example between the patient's arms and body) must be avoided, for example by separation with dry gauze.
►Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator.

PREPARATION OF THE DEVICES: ASSEMBLY AND DISASSEMBLY

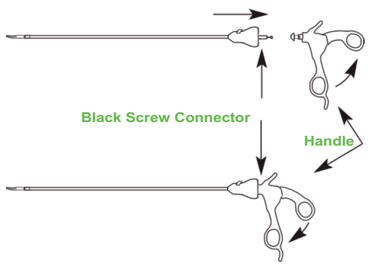
XPRESS LOCK© ASSEMBLY/ DISASSEMBLY

1. Push the insert into the handle's sheath such that the insert fully seats into the sheath. Some rotation of the tip may be necessary to align the tip notches and outer sheath slots.

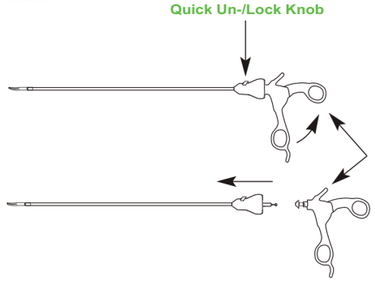
2. While holding the sheath, rotate the insert, with jaws closed counter clockwise 45° until tight.
The device cannot be assembled further if the tip is not seated correctly. If the insert spins more than 45°, ensure the notches are fully inserted into the sheath slots.



3. Open the handle completely and insert the sheath assembly into the handle. Tighten the sheath by closing the handle. When hearing the „click" the instrument is assembled correctly. The jaw tips must be closed to ensure proper fit into handle.



4. To disassemble, open the handle completely. Loosen the sheath by pressing the quick locking knob on the black screw connector. Then slide the sheath away from handle. While holding the sheath, rotate the insert clockwise 45° until loosened. Slide the insert from sheath.

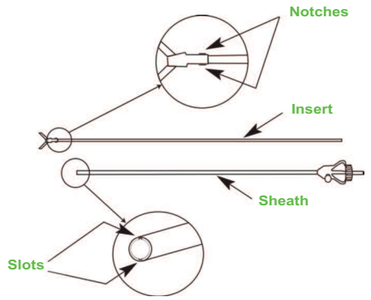


5. Clean and sterilize insert, sheath and handle immediately.

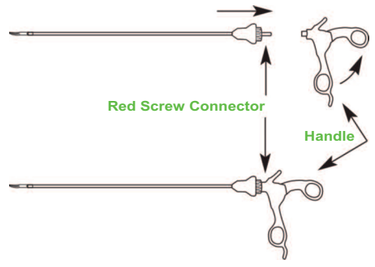
SECULOCK© ASSEMBLY/ DISASSEMBLY

1. Push the insert into the handle's sheath such that the insert fully seats into the sheath. Some rotation of the tip may be necessary to align the tip notches and outer sheath slots.

2. While holding the sheath, rotate the insert, with jaws closed counter clockwise 45° until tight.
The device cannot be assembled further if the tip is not seated correctly. If the insert spins more than 45°, ensure the notches are fully inserted into the sheath slots.



3. Open the handle completely and insert the sheath assembly into the handle. Tighten the sheath by turning the red coloured screw connector. The jaw tips must be closed to ensure proper fit into handle.

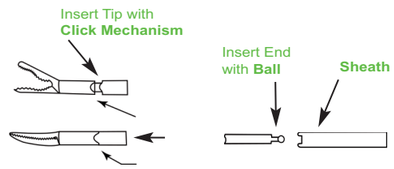


4. To disassemble, open the handle completely. Loosen the sheath by turning the red connector. Then slide the sheath away from handle. While holding the sheath, rotate the insert clockwise 45° until loosened. Slide the insert from sheath.

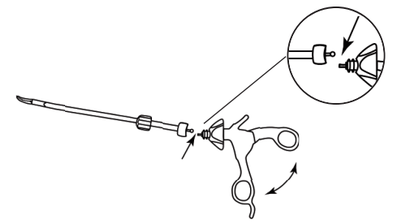
5. Clean and sterilize insert, sheath and handle immediately.

ENDO LOCK© ASSEMBLY/ DISASSEMBLY

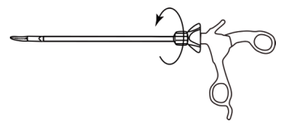
1. Slide the insert into the sheath. Notice the tongue and groove configuration. The insert should snap firmly into the shaft.



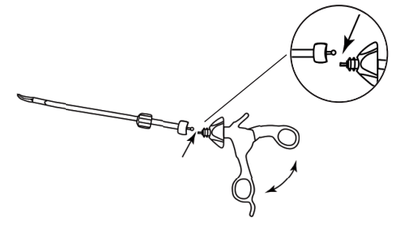
2. With the insert jaw closed and the handle open (just like you would like to open a pair of scissors), place the „ball" of the insert into the cutout of the handle; then squeeze the handle shut and keep it shut. The jaw tips must be closed to ensure proper fit into the handle.



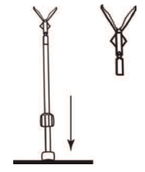
3. Turn the nut counter clockwise onto the handle and the device is ready to use.



4. To disassemble, unscrew the nut on the handle clockwise. Open the handle (just like you would like to open a pair of scissors) and lift the „ball" of the insert out of the cutout area.



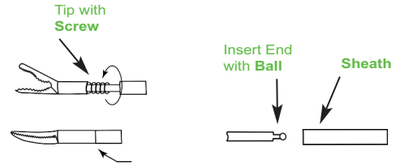
Firmly grasping the sheath with both hands, press the little „ball" on a hard surface until the insert detaches from the sheath. Pull the insert out of the sheath.



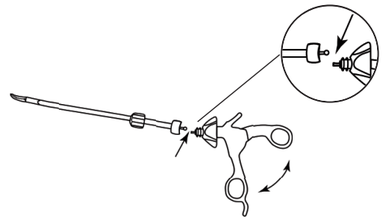
5. Clean and sterilize insert, sheath and handle immediately.

SYSTEM CS© ASSEMBLY/ DISASSEMBLY

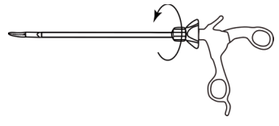
1. Remove the black nut on the handle. Put the insert into the sheath tightly fasten it by screwing the thread down completely.



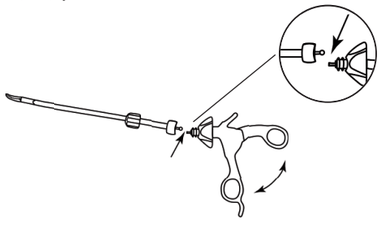
2. With the insert jaw closed and the handle open (just like you would like to open a pair of scissors), place the „ball" of the insert into the cutout of the handle; then squeeze the handle shut and keep it shut. The jaw tips must be closed to ensure proper fit into the handle.



3. Turn the nut counter clockwise onto the handle and the device is ready to use.



4. To disassemble, unscrew the nut clockwise, open handle completely and detach the insert/ sheath from the handle. Unscrew the insert from the sheath and separate them fully.



5. Clean and sterilize insert, sheath and handle immediately.

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REPROCESSING

WARNING

The following instructions only apply to reusable Ackermann products.

Please note that any deviation from these instructions, including the use of cleaners / detergents not specifically indicated in these instructions will require an evaluation of device-specific efficacy and suitability of the actually performed cycle. Respective evaluation usually requires equipment qualification and device specific performance qualification / Validation.

LIMITATIONS ON REPROCESSING

The useful life of these devices depends on many factors including, the method and duration of each use, and the handling between uses. Ackermann instruments have been validated in accordance with processes defined within the current state of the art, with a minimum of 50 reprocessing cycles. However, in view of the design, materials used and the intended use of the product, a maximum limit cannot be defined for the number of cleaning, disinfection or sterilization cycles that may be possible. Instruments for electrosurgery are by nature subject to increased wear, depending on the type and time of use. Careful inspection and functional tests of the device before each use is mandatory in determining the end of serviceable life for the medical device.

REPROCESSING INSTRUCTIONS

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard of hospital hygiene and sterilization technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilization is actually performed using appropriate equipment, materials, and personnel to achieve the desired result.
Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

WARNING

Before initial use and any subsequent use, all reusable Ackermann products have to be subjected to reprocessing as described in the following sections.
Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

PREPARATION PRIOR TO FIRST USE

The reusable Ackermann products are delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use.

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

PREPARATION AT THE POINT OF USE PRIOR TO REPROCESSING

Remove all traces of contamination and disassemble the instrument immediately after use to avoid incrustation. Do not use fixative agents or hot water (>40°C). Avoid using a metal brush, steel wool or other cleaning devices containing metal in order to avoid risk of insulation damage or corrosion. Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container.

CLEANING

WARNING

Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or in inadequate sterilization.

MANUAL PRE-CLEANING

The fully dismantled instruments shall be brushed under cold water until all visible contamination is removed. After manual brushing, rinse the lumen of the sheath via its flushing port with a water jet pistol (static pressure above 4 bar) for at least 10 seconds.

AUTOMATED CLEANING

Associated parts are to be stored together in order to facilitate a subsequent identification. Make sure that instruments do not contact each other. Devices from different materials such as titanium, brass, aluminium, stainless steel, etc. need to be cleaned separately in order to avoid formation of a rust film. Composite instruments particularly stainless steel combined with ceramics) need to be placed with sufficient distance to other products so they do not break due to the pressure of different thermal expansions.

RECOMMENDED PROCESS-EQUIPMENT

►Washer: Miele Type G7836 CD
►Cleaners: TWIN PH10 and TWINZYME (Borer Switzerland)

AUTOMATED CLEANING CYCLE

►Two-component alkaline-enzymatic Cleaning Program:
►3 min pre washing with cold tap Water
►Drain
►10 Min washing at 45°C w tap water and
►0,3% dosing TWIN PH10 at 35°C
►0,2% dosing TWIN ZYME at 40°C
►Drain
►2 min intermediate rinsing with warm deionised water (>30°C)
►Drain
►1 min intermediate rinsing with cold deionised water
►Drain
►5 min Thermal disinfection at >90°C
►30 min Drying

MAINTENANCE

Apply a small amount of high-grade surgical lubricant on all joints or other moveable parts which are supposed to move smoothly. Sort out all blunt or damaged instruments. Clearly damaged instruments (cracks on the insulation, breakage, strongly bleached polymer handles or coatings) are NOT to be reused but repaired or disposed of.

TESTING AND INSPECTION

All of the functional tests and inspections described in this manual must be conducted as part of every reprocessing procedure prior to sterilization of the devices. Failure in any of respective testing indicates that the device has passed its useful life and should be replaced.

Jointed instruments are to be tested for ease of movement (avoid too much backlash). The functionality of ratchet mechanisms needs to be checked. All instruments: visually check for damage and wear. Blades should be even and without notches. Long and narrow instruments (especially jointed instruments) should be particularly checked for damages. If instruments are part of a larger set they are to be checked together with all associated components.
Carefully inspect the insulation for damages and surface integrity.

WARNING

In case of present or suspected damage to the devices, do not try to repair the instrument. Avoid any further use of damaged instruments!

PACKAGING

Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607 / ANSI/ AAMI ST79 / AAMI TIR12:2010, for example, disposable sterilization packs (single or double packs) temperature resistant up to at least 137°C (279°F) and sufficient steam permeability, which provide sufficient protection against mechanical damage, or sterilization containers which need to be maintained according to the manufacturer's instructions.

STERILIZATION

WARNING

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Sterilization is preferably performed by steam sterilization. The following cycles has been validated in accordance with internationally harmonized standards in regard to its suitability and efficacy for the devices
fractionated pre-vacuum Cycle

132°C, 4 mins (wrapped), minimum 20 mins drying
or
134°C, 4 mins (wrapped), minimum 20 mins drying

Other reprocessing methods may also be suitable, but individuals or hospitals who do not reprocess the products according to the recommended instructions, are advised to validate any alternative reprocessing procedure.

STORAGE

Store instruments secured against mechanical damage. Use additional wrapping to protect against dust. Do not stack instruments which are packed sterile; especially do not place heavy items on top in order to avoid damage to the sterile packaging of other instruments.

ADDITIONAL INFORMATION

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

APPENDIX

All product codes covered by these instructions are listed in the following table:

XPRESS LOCK©

REF

INSERTS

11-1645XPI	13-1311XPI	13-1325XPI-45	13-1339XPI-45	13-1354XPI-45	13-1416XPI-45	13-1475XPI-45	13-1542XPI-45	13-1585XPI-45
11-1645XPI-45	13-1311XPI-45	13-1326XPI	13-1340XPI	13-1375XPI	13-1417XPI	13-1480XPI	13-1543XPI	13-1590XPI
11-1650XPI	13-1312XPI	13-1326XPI-45	13-1340XPI-45	13-1375XPI-45	13-1417XPI-45	13-1480XPI-45	13-1543XPI-45	13-1590XPI-45
11-1650XPI-45	13-1312XPI-45	13-1327XPI	13-1341XPI	13-1376XPI	13-1418XPI	13-1485XPI	13-1544XPI	13-1595XPI
13-0530XPI	13-1313XPI	13-1327XPI-45	13-1341XPI-45	13-1376XPI-45	13-1418XPI-45	13-1485XPI-45	13-1544XPI-45	13-1595XPI-45
13-0530XPI-45	13-1313XPI-45	13-1328XPI	13-1342XPI	13-1377XPI	13-1419XPI	13-1490XPI	13-1545XPI	13-1600XPI
13-1300XPI	13-1314XPI	13-1328XPI-45	13-1342XPI-45	13-1377XPI-45	13-1419XPI-45	13-1490XPI-45	13-1545XPI-45	13-1600XPI-45
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13-1303XPI-45	13-1318XPI	13-1332XPI	13-1346XPI	13-1381XPI	13-1455XPI	13-1525XPI	13-1550XPI	13-1612XPI
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13-1305XPI-45	13-1320XPI	13-1334XPI	13-1348XPI	13-1409XPI	13-1461XPI	13-1535XPI	13-1560XPI	13-1645XPI
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13-1308XPI	13-1322XPI-45	13-1336XPI-45	13-1350XPI-45	13-1412XPI-45	13-1466XPI-45	13-1537XPI-45	13-1570XPI-45	13-1655XPI-45
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13-1309XPI-45	13-1324XPI	13-1338XPI	13-1353XPI	13-1414XPI	13-1470XPI	13-1541XPI	13-1580XPI	
13-1310XPI	13-1324XPI-45	13-1338XPI-45	13-1353XPI-45	13-1414XPI-45	13-1470XPI-45	13-1541XPI-45	13-1580XPI-45	
13-1310XPI-45	13-1325XPI	13-1339XPI	13-1354XPI	13-1416XPI	13-1475XPI	13-1542XPI	13-1585XPI	

SHEATHS

13-1356XP	13-1356XP-45	13-1357XP	13-1357XP-45					

HANDLES

13-1367XP	13-1368XP							

SECULOCK©

REF

INSERTS

11-1645SQI	13-1312SQI-45	13-1329SQI-26	13-1345SQI-26	13-1409SQI	13-1466SQI-45	13-1542SQI	13-1595SQI-45	
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SHEATHS

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HANDLES

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13-1365SQ	13-1367SQ-ALT	13-1368SQ-ALT	13-1369SQ	13-1383SQ	13-1384SQ	13-1390SQ	

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INSERTS

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HANDLES

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SYSTEM CS©

INSERTS

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13-1301CSI-26	13-1316CSI	13-1333CSI	13-1346CSI-45	13-1381CSI	13-1460CSI	13-1530CSI-26	13-1555CSI-45	13-1607CSI-22
13-1301CSI-45	13-1316CSI-26	13-1333CSI-26	13-1347CSI	13-1381CSI-26	13-1460CSI-26	13-1530CSI-45	13-1560CSI	13-1612CSI
13-1302CSI	13-1316CSI-45	13-1333CSI-45	13-1347CSI-26	13-1381CSI-45	13-1460CSI-45	13-1535CSI	13-1560CSI-26	13-1612CSI-26
13-1302CSI-26	13-1316CSIDB	13-1334CSI	13-1347CSI-45	13-1382CSI	13-1461CSI	13-1535CSI-26	13-1560CSI-45	13-1612CSI-45
13-1302CSI-45	13-1317CSI	13-1334CSI-26	13-1348CSI	13-1382CSI-26	13-1461CSI-26	13-1535CSI-45	13-1565CSI	13-1620CSI
13-1303CSI	13-1317CSI-26	13-1334CSI-45	13-1348CSI-26	13-1382CSI-45	13-1461CSI-45	13-1536CSI	13-1565CSI-26	13-1620CSI-26
13-1303CSI-26	13-1317CSI-45	13-1335CSI	13-1348CSI-45	13-1409CSI	13-1465CSI	13-1536CSI-26	13-1565CSI-45	13-1620CSI-45
13-1303CSI-45	13-1318CSI	13-1335CSI-26	13-1349CSI	13-1409CSI-26	13-1465CSI-26	13-1536CSI-45	13-1570CSI	13-1621CSI
13-1304CSI	13-1318CSI-26	13-1335CSI-45	13-1349CSI-26	13-1409CSI-45	13-1465CSI-45	13-1537CSI	13-1570CSI-26	13-1621CSI-26
13-1304CSI-26	13-1318CSI-45	13-1336CSI	13-1349CSI-45	13-1411CSI	13-1466CSI	13-1537CSI-26	13-1570CSI-45	13-1621CSI-45
13-1304CSI-45	13-1322CSI	13-1336CSI-26	13-1350CSI	13-1411CSI-26	13-1466CSI-26	13-1537CSI-45	13-1571CSI	13-1622CSI
13-1305CSI	13-1322CSI-26	13-1336CSI-45	13-1350CSI-26	13-1411CSI-45	13-1466CSI-45	13-1540CSI	13-1571CSI-26	13-1622CSI-26
13-1305CSI-26	13-1322CSI-45	13-1337CSI	13-1350CSI-45	13-1412CSI	13-1467CSI	13-1540CSI-26	13-1571CSI-45	13-1622CSI-45
13-1305CSI-45	13-1323CSI	13-1337CSI-26	13-1351CSI	13-1412CSI-26	13-1467CSI-26	13-1540CSI-45	13-1580CSI	13-1625CSI
13-1306CSI	13-1323CSI-26	13-1337CSI-45	13-1351CSI-26	13-1412CSI-45	13-1467CSI-45	13-1541CSI	13-1580CSI-26	13-1625CSI-26
13-1306CSI-26	13-1323CSI-45	13-1338CSI	13-1351CSI-45	13-1413CSI	13-1470CSI	13-1541CSI-26	13-1580CSI-45	13-1625CSI-45
13-1306CSI-45	13-1324CSI	13-1338CSI-26	13-1353CSI	13-1413CSI-26	13-1470CSI-26	13-1541CSI-45	13-1585CSI	13-1650CSI
13-1307CSI	13-1324CSI-26	13-1338CSI-45	13-1353CSI-26	13-1413CSI-45	13-1470CSI-45	13-1542CSI	13-1585CSI-26	13-1650CSI-26
13-1307CSI-26	13-1324CSI-45	13-1339CSI	13-1353CSI-45	13-1413CSI-48	13-1475CSI	13-1542CSI-26	13-1585CSI-45	13-1650CSI-45
13-1307CSI-45	13-1325CSI	13-1339CSI-26	13-1354CSI	13-1416CSI	13-1475CSI-26	13-1542CSI-45	13-1590CSI	13-1655CSI
13-1308CSI	13-1325CSI-26	13-1339CSI-45	13-1354CSI-26	13-1416CSI-26	13-1475CSI-45	13-1543CSI	13-1590CSI-26	13-1655CSI-26
13-1308CSI-26	13-1325CSI-45	13-1340CSI	13-1354CSI-45	13-1416CSI-45	13-1480CSI	13-1543CSI-26	13-1590CSI-45	13-1655CSI-45
13-1308CSI-45	13-1326CSI	13-1340CSI-26	13-1355CSI	13-1417CSI	13-1480CSI-26	13-1543CSI-45	13-1595CSI	13-1660CSI
13-1309CSI	13-1326CSI-26	13-1340CSI-45	13-1355CSI-26	13-1417CSI-26	13-1480CSI-45	13-1544CSI	13-1595CSI-26	13-1660CSI-26

SHEATHS

13-1356CS	13-1356CS-26	13-1356CS-45	13-1357CS	13-1357CS-26	13-1357CS-45	

HANDLES

13-1367CS	13-1367CS-ALT	13-1368CS	13-1369CS	13-1383CS	13-1384CS	13-1389CS	13-1390CS	

SYMBOLS USED ON LABELLING (ACC. DIN EN 980 / DIN EN ISO 15223-1)

LEGAL MANUFACTURER	CONSULT INSTRUCTIONS FOR USE	NON-STERILE	DO NOT USE IF PACKAGE IS OPENED OR DAMAGAED
MANUFACTURING DATE	PRODUCT NUMBER	KEEP OUT OF DIRECT SUNLIGHT	PROTECT AGAINST MOISTURE
BATCH CODE	CAUTION, CONSULT ACCOMPANYING DOCUMENTS	PRESCRIPTION USE ONLY	**KIWA** BELGELENDIRME HIZMETLERI A.Ş. İTOSB 9. CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL / TÜRKİYE

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