

Surgical Kit CIR's System Instructions For Use (IFU)

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Instructions for use - Surgical Kit CIR's System



CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST !

INTENDED USE:

Drills are intended for use in the dental implant surgery application preparing the jawbone for a dental implant. Products are compatible for use with existing surgical accessories for routine Dental surgery. Ritter Implants drills and tools are intended for use only by certified dentists and authorized persons with specific implant training. Ritter surgical kits are used for two-stage and one-piece implantation processes. The tools and drills are made of different alloys of stainless steel. They are supplied with the understanding that only Ritter Implants surgical instruments, which complement each implant, will be used during surgery. If these conditions are not met, the manufacturer will refuse to accept responsibility.

INDICATIONS FOR USE:

The Ritter Implants are intended for simple or multiple replacements of lost teeth and provide a way to attach the prosthetic pieces in totally or partially edentulous patients.

INSTRUCTIONS FOR MAINTAINANCE OF SURGICAL TOOLS PRIOR TO FIRST-TIME SURGICAL USE:

Stage 1:

Light cleaning and rinsing - surgical tools should be dipped in detergent, rinsed with distilled water, and dried immediately and meticulously.

Stage 2: Sterilization - Drills should be sterilized in an autoclave between 134° -137° C/275° F for 18 minutes.

Stage 3: During Use - surgical tools should be soaked in a sterile saline solution until the cleaning stage.

INSTRUCTIONS FOR CLEANING AND STORAGE OF SURGICAL TOOLS AFTER USE

Stage 1: Cleaning - Surgical tools should be brushed with detergent to remove any remaining blood or tissue.

Stage 2: Ultrasonic Cleaning - Surgical tools should be cleaned in an ultrasonic bath with appropriate detergent- (Note: During ultrasonic cleaning, contact between surgical tools should be avoided)

Stage 3: Rinsing - Surgical tools should be rinsed, preferably with distilled water, and dried immediately and meticulously.

Stage 4: Lubrication [required if more than 4 weeks of storage is expected] - Surgical tools should be soaked for 10 seconds in dental oil, and then removed from solution and left to dry for 30 seconds without rinsing or towel drying, and then placed in surgical kit.

Stage 5: Sterilization - Surgical tools should be sterilized in an autoclave between 134°-137° C/275° F for 18minutes.

Stage 6: Storage/Use - At this stage, kits are ready for long-term storage; they can be used immediately upon opening the kit.

RECOMMENDATIONS:

- Drilling/Cutting tools should be used for a maximum of 6-10 cycles.
- Sterilized water should be used in order to avoid surface stains.

Ritter Implants surgical kits are designed for the surgical protocol and procedure of the following implant categories:



SB/LA Spiral Implant
SNAP & NL-SNAP



QSI & NL-QSI
Ri-Quadro Spiral
Implant



TFI
Ri-Twin Fissure
Implant



MCI
Mono one-piece
Implant

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CAUTION: BEFORE USING TOOLS AND DRILLS THE IMPLANTOLOGIST MUST HAVE CLARIFIED THE CLINICAL CASE .

GUIDE TO CHOOSING THE PROPER IMPLANT:

After making a preliminary diagnosis, an X-ray and/ or CT, in conjunction with a transparency that displays the necessary measurements, should be used to determine the dimensions of the implant suitable for the site in question. As a general rule, the widest and longest implant suitable for a particular site (density and dimensions of bone, dimensions of gums) should be used, in order for rehabilitation to be most effective. Another general rule is that implant and abutment combinations offer the greatest range of rehabilitation options. The use of the integrated implant offers some advantages that a appeal to certain patients, and are appropriate for them. The choice of an integrated implant/abutment (one-piece) requires immediate loading and rehabilitation, and cementing of the restoration device. There is no affixing of the abutment by screw, and no choice as to the structure of the abutment. That choice is made beforehand. In a two-stage implantation, if there is a need for immediate loading, the spiral conical implant (QSI), which has good retention from the outset, should be used. In the lower jaw in Type 1 hard bones the SB/LA SNAP, TFI, QSI implants are suitable. In the front, single-rooted teeth and in the upper teeth between tooth 4 and tooth 7, where the sinus cavity is found, wide conical implants are recommended in order to reduce pressure on the base of the sinus. When the bone is very wide, and the sinus cavity is distant, any implant can be used. When the bone is narrow, a wide implant should not be used. Following extraction, if the bone is good, a spiral implant (QSI or SNAP), or immediate loading, is appropriate.

TFI: A Twin Fissure Implant - available in narrow (3,3 mm) up to (5 mm) platforms. Recommended for use in hard bone type 1, anterior area.

SB/LA Spiral Implant (SNAP), QSI & NL-QSI:

A Spiral conical implant, with deep, wide gap threads, especially high-sharp-thread edges and a grooved neck. Its advantages are: the deep threads increase the surface area, and hence improve the retention of the implant; while the implant is inserted by rotations into the bone, the sharp thread edges generate their path in the bone tissue. As deep as the implant is inserted the bone becomes more condense, due to the conical structure of the implant; excellent initial retention.

MCI:

A mono one-piece slim integral implant intended for immediate loading. It is appropriate for Types 1, 2 & 3 bones, and also for narrow and buccal plates, on narrow ridges, and between closely spaced implants or teeth. It is also used between permanent implants, which need relief during their osseo-integration. Temporary restoration is cemented upon the middle MCI implant which eliminates the stress upon the neighbouring implants. This implant is used in space limited areas.



- DRILLING PROCEDURE -

ALL IMPLANTS: After good surgical exposure of the bony surface, the position for the implant should be determined and a guide hole should be made using our round-head bur, taken down into the cortical bone to the level of the neck beneath the bur head. Do not attempt to drill deeper with the round bur using the guidehole for position; the color-coded drill bits will be utilized to drill the hole to the desired depth. The color coding on the bits indicates the diameter of the bit. Almost all drilling (Excluding all MCI) should commence using the 2.0 millimeter bit or lance drill. The bits are used ingraduated order to slowly increase the diameter of the implant hole until the desired diameter is reached. This will allow safe progression and decrease trauma to the surrounding bone structures. The accurate depth of the hole is determined by the length of each particular implant and is indicated by the depth lines around each bit, in order to allow good position of the implant in the bone so that its end is flush with the alveolar ridge.

QSI/SNAP- PROTOCOL:

The best conical hole for the planned conical implant is achieved by using the appointed conical drilling bit. All bits, with the exception of the final regular bit, are inserted in turn till the required depthline reaches the alveolar ridge. The final regular bit is inserted gently to a depth of only the necessary situation. The drilling protocols of tapered holes are presented in Table A. Ritter conical drills CDEP have a Stopper-system included which assures correct drilling depth, preventing drilling deeper than required.

The most efficient method of drilling has been found to be achieved through the use of conical drilling bits. We highly recommend that our customers acquire the conical drilling bits. The conical drilling bit for each diameter is suitable for every implant length in that diameter. Where the conical drilling bits are not available, it is possible to achieve the desired tapering of the hole by re-drilling with two slightly larger bits taken down only to a partial depth. The first bit, slightly larger than the bit used to reach the desired depth of the implant hole, drills only 2/3 of the total depth, and the second, slightly larger than the first, drills only 1/3 of the depth, thus creating a staged or conical tapered hole.

TFI - PROTOCOL:

The final diameter of the hole should be approx. 0.5 mm smaller than the implant diameter (e.g. for an implant with a diameter of 3.75 mm, the final bit size would be 3.2 mm). Table B summarizes the final color-coded drill for each implant.

Implant Diameter	NL-3	NL-3.3	3.75	4.2	5.0	6.0
Color Code	white	red	blue	green	black	brown
Preceding regular drills CDEP	--	1	1	2	3	4
Conical Bit width CDEP	--	2.8	3.2	3.2-3.65	3.2-4.5	3.2-5.4
Final regular drill with max. depth / accordingly to the length of the implant	2.5	2.8	3.2	3.65	4.5	5.4



Implant Diameter		3.3	3.75	4.2	5.0	
Color Code		red	blue	green	black	brown
Preceding regular drills CDEP		1	1	2	3	
Conical Bit width CDEP		2.8	3.2	3.2-3.65	3.2-4.5	
Final regular drill with max. depth / accordingly to the length of the implant		2.8	3.2	3.65	4.5	



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MCI - PROTOCOL:

Preferably, the 2.4mm conical drill bit is inserted till the required depth line reaches the alveolar ridge. Table C summarizes the brief drilling procedure when using the conical drill bit. Where the 1.8-2.4mm and the 2.0-3.2mm conical drill bit is not available, it is possible to use the regular drill bits instead, but it should be inserted only till the depth line below the nominal one reaches the alveolar ridge.

Tables C also summarize the drilling sequence and depth for each implant when not using the conical drill bit. (Only lance drills with 2.0-2.8 mm are necessary).



CAUTION: As the lance drills have no stopper-system included, the drilling process must be done carefully in order to drill not deeper than 8mm!



Table C: The recommended conical drills for each implant diameter:	MCI 2.8	MCI 3.2	Implant length 10 mm	Implant length 11.5 mm	Implant length 13 mm
Implant Diameter	2.8	3.2			
Max. drilling depth in mm	--	--	8	10	11.5
Preceding drills	1	2			
Lance drill	2.0	2.0-2.8			
Final Regular Bit with max. depth / accordingly	2.0	2.8			



CAUTION:

All conical drill bits are characterized by drilling through the bone along the entire length of the drill that is positioned inside the gums. This is as opposed to the regular drill bit, which only drills through the bone using the frontal lower tip. The same time, its side helical blades slide along the wall of the hole without any significant radial forces. The use of conical drill bits causes extreme radial pressure, creating the necessity for gentle, probing drilling instead of constant drilling. This gradual drilling should include the use of a low torque.

The maximum rpm (rounds per minute) is dependent upon both the type of one and the drilling diameter. Do not exceed 450 rpm and torque of 35 Ncm. Drilling should be accompanied by intensive irrigation. First you must drill with drill bits in a slow gradient - first the 2.0mm bit, then 2.8mm bit and so on as necessary. The conical drill bit is only to be used at the end of the drilling process so that only a small amount of bone will have a quicksand effect. The hard bone drills may be used to widen the crestal bone at the end of the drilling sequence (CD 3.75-6.0).

EXAMPLE: When desired to insert a 6.0mm implant one must use the final regular drill CDEP-5.4 for the 6.0mm implant. Pausing periodically during the drilling allows both the blade and the bone to cool down. It also allows for the removal of bone fragments as well as the control necessary at the appropriate rpm. The drill should be moved up and down during drilling to prevent too much heat and pressure or even microsis. (Branemark Bone Dancing Method)

NOTE: Drills should not be used more than 6-10 cycles. They have to be replaced after their life-time cycle.

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Ritter Implants kits:

RIBUS-SE, Ritter - CIR Surgical Kit USA/Starter EXT

RIBEU-PE, Ritter - CIR Surgical Kit Europe/Professional incl. NL Tools

RIB-PROS, Ritter - Prosthetic Kit USA

NL-RIBUS-PE, Ritter - CIR Surgical Kit USA/Prof. EXT - NL

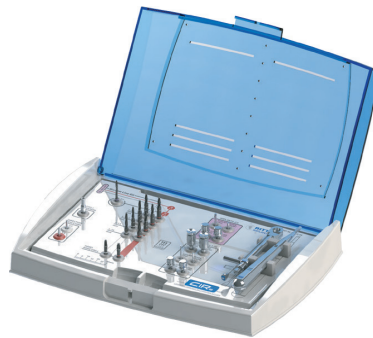


RIBUS-SE

The Kits are consisting of the following products and their specific usage:



RIBEU-PE



NKL-RIBUS



RIB-PROS

ITEM NO. / TOOL DRILL	DESCRIPTION	FUNCTION - how to work / used by
CDEP drills all Diameter and lenght	Conical Drill with integrated Stopper-System function	adapted to handpiece with SD-coupling / surgical motor. for drilling the implant hole / dentist
MMIB / NL-MMIB	Motor Mount for Implant with ball friction to hold implant normal and narrow line	for insertion / loading the implant to the mouth attached with SD coupling to handpiece/surgical motor/ dentist
RDI / NL- RDI Long and short	Implant driver with head for ratchet normal and narrow line	For insertion of implant with ratchet/ dentist
HHDA / Long and short	Abutment Hand Driver	for fixing / assembling abutments by hand torque. LAB and dentist
MMA / Long and short	Abutment Motor Mount	for fixing / assembling abutments by motor LAB and dentist
DEX	Drill extender	extends the length. used with all items with SD coupling head for handpiece / LAB and dentist
CD drills	Hard bone drills	drills for widening the crestal or hard bone / dentist
DEP drills	Parallel drills, non conical	adapted to handpiece with SD-coupling / surgical motor. for drilling the implant hole / dentist
DELD	Long thin pilot drill	first drill to initiate the drilling process
DP	Direction pins	for improving the depth and parallelity of the hole/ drilled angle / dentist
TRU / RWH	Ratchet / with (TRU) or without torque measurement (RWH)	for fixing all items with ratchet head / LAB and dentist
IDP	Implant Deep Probe	for improving the depth of the drilled cavity

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RIBEU-PE, Ritter - CIR Surgical Kit
Europe/Professional incl. NL Tools

This professional kit contains all tools
and drills which are necessary for placing
Implants with all diameters, incl.
Narrow Line (NL).

Conical Drills - External Irrigation (Ømm-Lmm)

- CDEP-4-5-6
- CDEP-4-5-8
- CDEP-4-5-10
- CDEP-4-5-11.5
- CDEP-4-5-13
- CDEP-4-5-16
- CDEP-3-65-6
- CDEP-3-65-8
- CDEP-3-65-10
- CDEP-3-65-11.5
- CDEP-3-65-13
- CDEP-3-65-16
- CDEP-3-2-6
- CDEP-3-2-8
- CDEP-3-2-10
- CDEP-3-2-11.5
- CDEP-3-2-13
- CDEP-3-2-16
- CDEP-2-8-10
- CDEP-2-8-11.5
- CDEP-2-8-13
- CDEP-2-8-16
- CDEP-2-5-10
- CDEP-2-5-11.5
- CDEP-2-5-13
- CDEP-2-5-16

Motor Mount for Implant Self Loading -Hex 2.0

- NL-MMIB-28
- NL-MMIB-22

Motor Mount for Implant Self Loading -Hex 2.43

- MMIB-28
- MMIB-22

Ratchet Driver for Implant Hex 2.0

- NL-RDI-L (long)
- NL-RDI-M (short)

Ratchet Driver for Implant Hex 2.43

- RDI-L (long)
- RDI-M (short)

Hand Hex Driver for prosthetics 1.29 Hex

- HHDA (long)
- HHDA-S (short)

Motor Mount for Prosthetics 1.29 Hex

- MMA-28
- MMA-22

Ratchet Driver for Prosthetics 1.29 Hex

- RDA-L (long)
- RDA-M (short)

Direction Pins for Implants (1.9Ømm/Ømm)

- DP-3.0
- DP-3.3
- DP-3.75
- DP-4.2
- DP-5.0
- DP-6.0

Hard Bone Drills for Implants (Ømm)

- CD-3.0
- CD-3.3
- CD-3.75
- CD-4.2
- CD-5.0

Drill Extender for external irrigation drills DEX

- Standard Drill 2.0 External Irrigation & Lance 2 in 1 (Ømm)
- DELD-2.0
- Standard Drill 2.8 External Irrigation (Ømm-Lmm)
- DEP-2.8-16

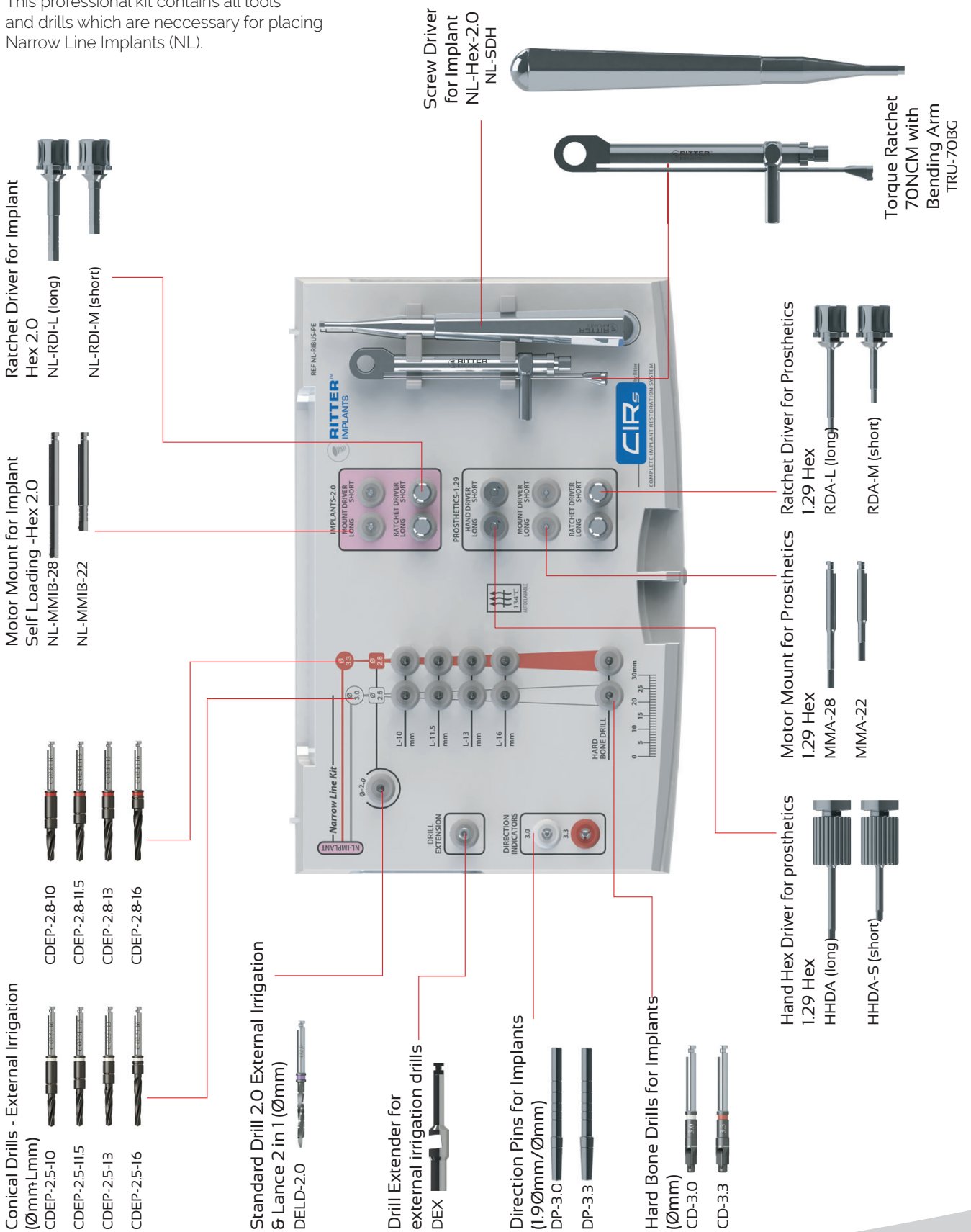
Torque Ratchet 70NCM with Bending Arm TRU-70BG

CIR 6

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NL-RIBUS-PE, Ritter - CIR Surgical Kit
USA/Prof. EXT - NL

This professional kit contains all tools
and drills which are necessary for placing
Narrow Line Implants (NL).



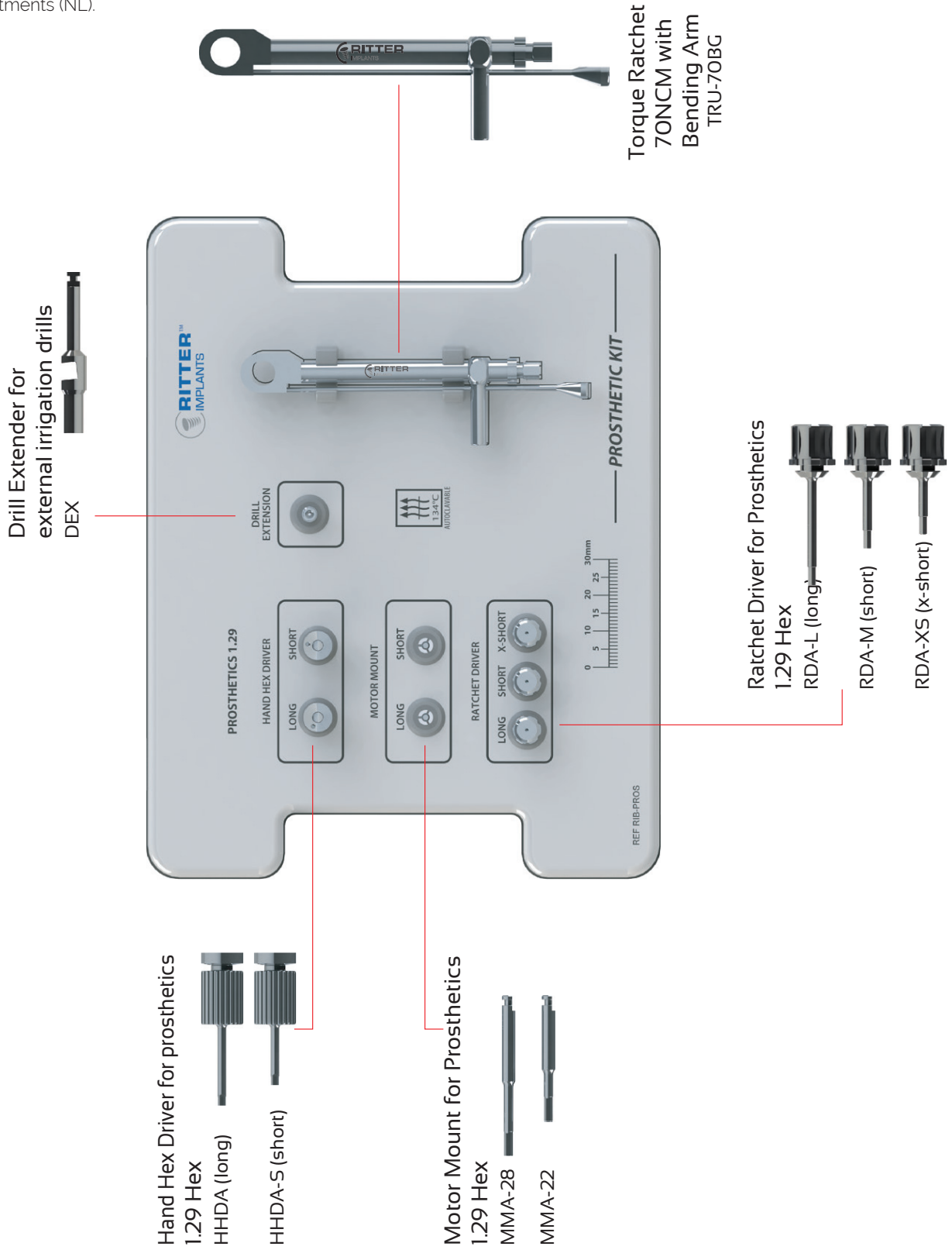
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RIB-PROS, Ritter - Prosthetic Kit USA



This tool kit contains all tools and mounts which are necessary for the laboratory works, incl. assembling Narrow Line abutments (NL).

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Drill Extender for external irrigation drills
DEX

Hand Hex Driver for prosthetics
1.29 Hex
HHDA (long)
HHDA-S (short)

Motor Mount for Prosthetics
1.29 Hex
MMA-28
MMA-22

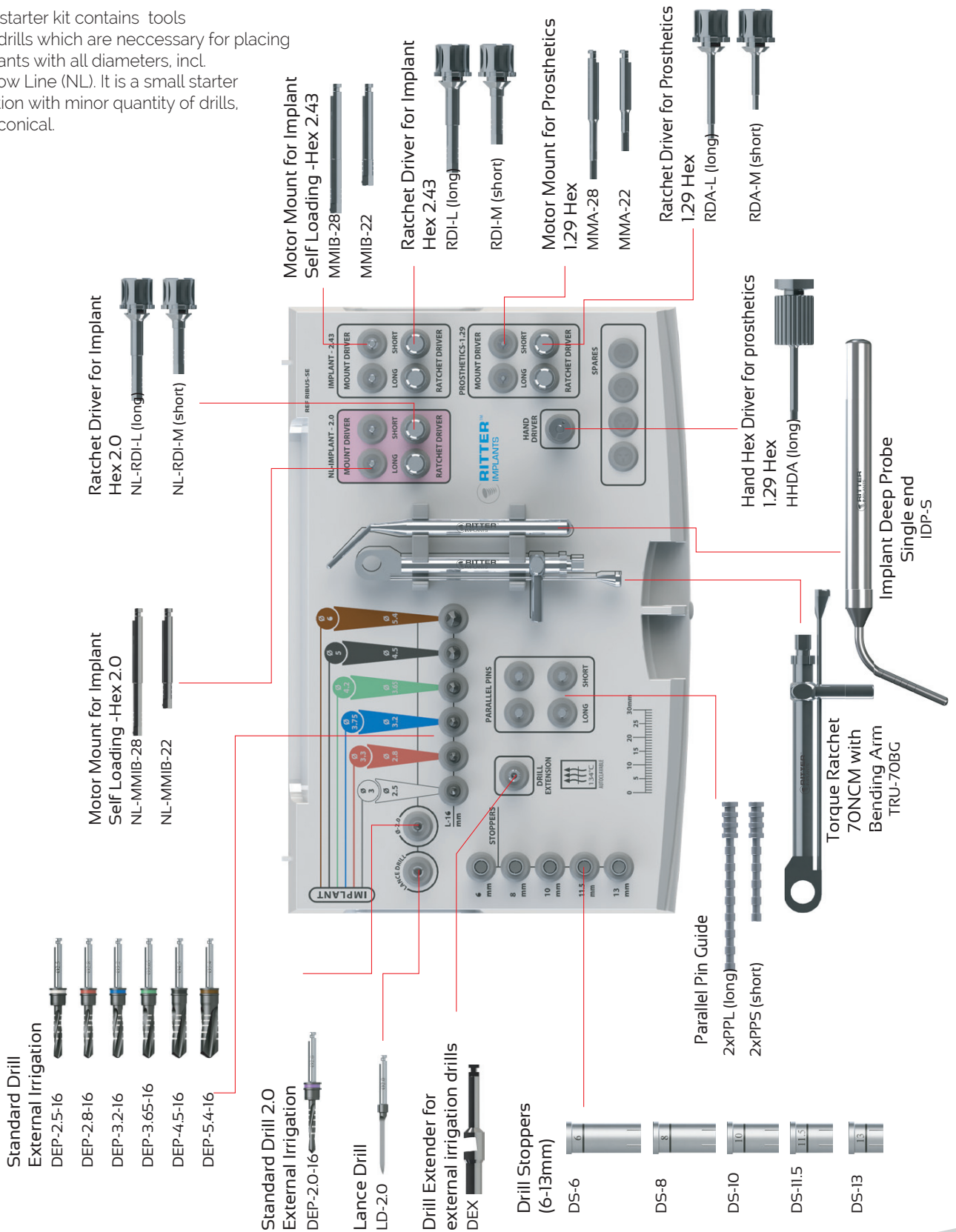
Ratchet Driver for Prosthetics
1.29 Hex
RDA-L (long)
RDA-M (short)
RDA-XS (x-short)

Torque Ratchet
70NCM with
Bending Arm
TRU-70BC

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RIBUS-SE, Ritter - CIR Surgical Kit USA/ Starter EXT

This starter kit contains tools and drills which are necessary for placing Implants with all diameters, incl. Narrow Line (NL). It is a small starter solution with minor quantity of drills, non conical.



CLEANING/STERILIZATION INFORMATION:

Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens. Clinically contaminated implants should not be cleaned and resterilized for reuse under any circumstances.

CLEANING: Use the following guidelines for cleaning products as drills, instruments and components: Disassemble multi-piece components, if applicable. Rinse with cool-to-lukewarm water for two-and-one-half minutes. For drills, flush the drill lumen with water to remove any remaining debris. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Ultra-Sonicate for 10 minutes. Rinse with tap water for three minutes. Kits, Trays, and Blocks - Remove all parts and insert from the tray. Clean parts per the above instructions. Thoroughly rinse the kits under running tap water to remove all visible soil. Use a soft bristle brush to clean the kits until all visible soil is removed. A syringe or pipe cleaner may be used to aid in the rinsing. Assure that all hard to reach areas are accessed. After the rinsing, prepare the enzymatic detergent following the manufacturer's specifications. Fully immerse the kit in the prepared detergent and allow the kit to soak in the detergent for a minimum of one minute. Following the soak use a damp cloth and/or a soft bristle brush to wipe and remove any excess debris/soil from each component. A syringe or a pipe cleaner may be used to aid in the cleaning. Rinse the kits with lukewarm tap water to eliminate all residual enzymes and detergent, thoroughly for a minimum of three minutes. Dry the components. Reassemble the contents of the kit and follow the guidelines for sterilization.

NOTE: This procedure should be performed after an instrument used during a surgery comes into contact with the surgical tray or prosthetic tray.

STERILIZATION:

Individual parts should be placed in appropriate autoclave or dry heat pouch prior to sterilization. When sterilizing parts within a kit, parts should be placed in appropriate locations and kit should be wrapped in sterilization wrap. The following sterilization parameters (method, time and temperature) are required to achieve a 10⁻⁶ sterile-assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded. To ensure autoclave is performing effective, periodic use of biologic indicators should be considered. Chemclave sterilization is NOT recommended for any Ritter Implants Dental products.

Tools, drills and parts individually pouched	Cycle Type	Temperature	Exposure time in Minutes	Drying Time in Minutes (only for kits)
	Gravity (steam)	121°C/250°F	40	--
Tools, drills and parts individually pouched or placed in surgical kit	Gravity (steam)	121°C/250°F	80	30
	Pre-Vacuum (steam)	132°C/270°F	3	30
	Pre-Vacuum (steam)	134C/273°F	18	30
	Dry-Heat	160°C/320°F	120	--













TECHNICAL INFORMATION: Procedure for Ritter Implants **angled abutments**.

NOTE: During implant placement, it is recommended to orient the flat of the internal hex of the implant to be opposite the angle correction. The pre-attached multi-purpose fixture mount can be used to index the internal hex of the implant. The flat side on the wall of the fixture mount will fine up with the flat side of the internal hex. **NOTE:** To put the abutment in the mouth use the HHDA abutment driver. The driver should be hand tightened (max. 30 Ncm) to the abutment to confirm adequate attachment of the tool to the abutment.

Use appropriate abutments and angulated components that correspond to the implant system being restored.

1. Remove the angled abutment from the abutment packaging in a sterile field. Hand tighten the abutment with the HHDA Abutment Hand Driver to confirm the attachment to the cone of the abutment. **2.** Thread dental floss through nose hole in the HHDA top. Utilizing the abutment Driver, deliver the abutment to the mouth. Aligning the angled abutment in the appropriate orientation for desired angulation correction. **3.** Use 1.27mm [0.50"] Hex Driver HHDA to hand tighten (max. 30 Ncm) the abutment retaining screw. A contra-angle hand piece with a 1.27mm MMA driver can also be used for initial delivery. The long MMA driver (MMA-28) must be used if the abutment delivery tool is attached to the abutment. The standard MMA driver (MMA-22) can be used if the abutment delivery tool is removed from the abutment. **4.** Verify with periapical radiograph that the abutment is seated completely into the implant and has engaged the internal hexagon. **5.** Tighten the abutment retaining screw to 30 Ncm with a calibrated torque wrench. The Torque Wrench TRU/RWH can be used with the abutment driver for ratchet RDA-L, removed from the abutment can be used RDA-M. **6.** If the abutments will not be immediately restored with a provisional or final restoration, it is recommended to place the abutment titanium Healing Cap. (HC-xx) to prevent irritation of the soft tissue and to prevent the ingress of material the screw access of the abutment cone. **NOTE:** The usage of ratchet RWH is recommended up to 35 Ncm maximum. More force will cause a break or malfunction of the ratchet head.

Symbols may be used on some international package labeling for easy identification.

Symbol	Description
	Sterilized using irradiation
 Single Use	Do not reuse
 CAUTION	Caution
	Consult instructions for use
	Do not use if package is damaged
	Use by
	Batch Code
	Catalogue number
	Do not resterilize
	Manufacturer
	CE Mark
	Symbol for "Use by Prescription only"

Ask for more Information and coming events

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