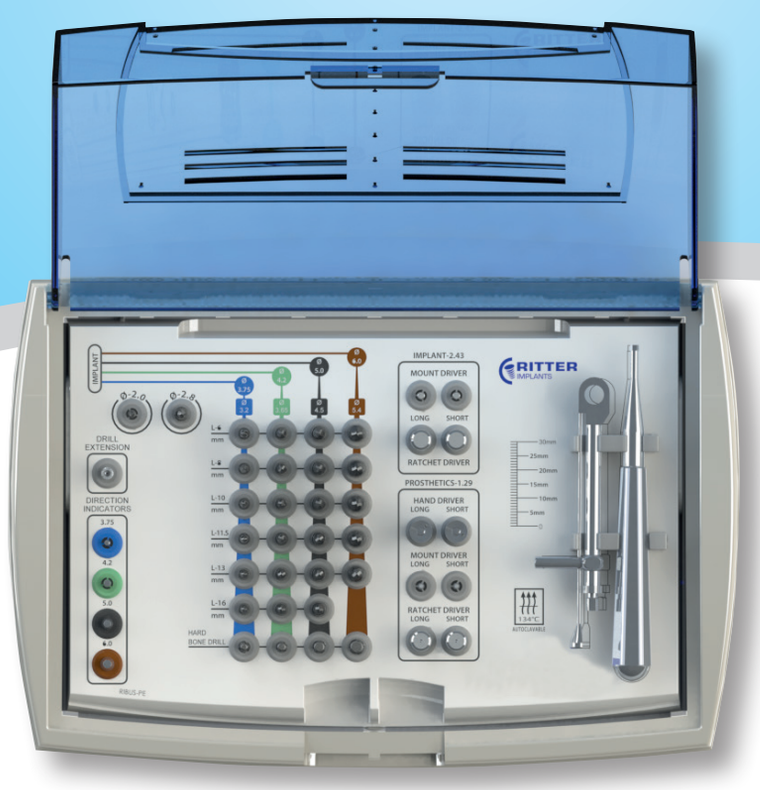
RITTER™ IMPLANTS

Surgical Kit System

Instructions For Use (IFU)

Version IFU I20-0002-2101EN
2021-09-30



V.IFU I20-0002-2101EN

CE 1023

Instructions for use - Surgical Kit System

CAUTION

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.

Cleaning/ disinfection/ sterilization (Prior to first time surgical use and after use):
For information on tools / drills / kits see page 16
For information on ratchets, see page 6/7

RECOMMENDATIONS:
• Drills 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

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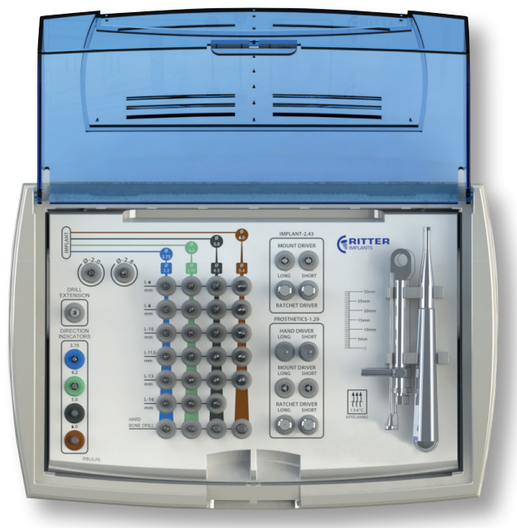
CAUTION

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

GUIDE TO CHOOSE THE PROPER IMPLANT:
After making a preliminary diagnosis, a 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 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, 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.

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.



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 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-sytem included which assures correct drilling depth, preventing drilling deeper than required. The drills of the guided system GSD reaches their final depth by tbeeing limited through the guiding drills sleeve.
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 conicail drilling bits are not available, it is possible to achieve the desired tapering of the hole by re-drilling with two slighter 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.

Table A: QSI and SB/LA Spiral Implants -SNAP-						
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

Table B: QSI and SB/LA Spiral Implants -SNAP- Guided					
Implant Diameter	NL-3	NL-3.3	3.75	4.2	5.0
Color Code	white	red	blue	green	black
Preceding regular drills GSD	--	1	1	2	3
Conical Bit width GSD	2.8	3.1	3.75	4.1	4.9
Final regular drill with max. depth / accordingly to the length of the implant	2.8	3.1	3.75	3.75	4.9

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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 dentalfloss 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 1.27mm0 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 Ratchet TRU 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 immedately 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: More force will cause a break or malfunction of the ratchet head.

CAUTION

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!

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

CAUTION

Use of torque ratchet:
Max. loading with hardened RA-shanks: 80 Ncm
Max. loading with non hardened RA-shanks: 40 Ncm

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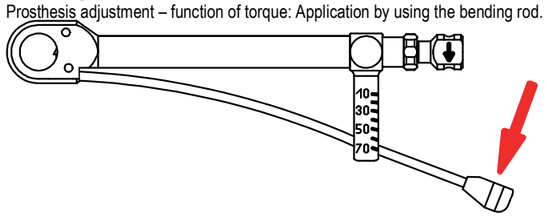
GB - Universal torque ratchet – instruction manual

NON STERILE

CE

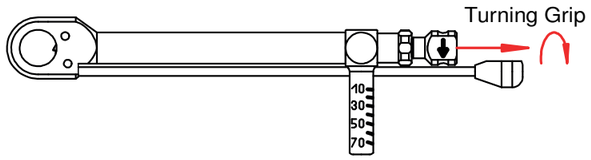
1. Intended use
Torque ratchet for inserting and removing dental screws with a defined torque. The torque function can be "blocked"; the blocked position enables greater torque to be transferred when placing implants, and allows connections to be loosened. The torque ratchet may only be used by trained dental specialists.

2. Handling
Prosthesis adjustment – function of torque: Application by using the bending rod. The torque will be read by means of the bending rod on the scale.



The requested torque will be achieved when the middle of the bending rod will be covered with the appropriate scale graduation mark.
ATTENTION: Reading should always be done directly from the top.
When the desired torque has been achieved, please relieve the bending rod again. Then, the bending rod will spring back into the starting position.

Surgical adjustment – blocked function: Use the torque without the bending rod.
Attention: The torque should not be charged over 100 Ncm.



3. Switching of the direction of rotation:
- pull the turning grip
- turn half way the turning grip
- release the turning grip

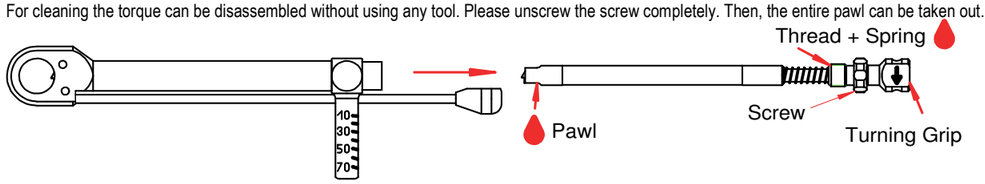
4. Exchanging of the tools
Pull the turning grip, then the tools can be taken out i.e. can be used. Then release the turning grip. Now, the tools can be used from both sides. If necessary, switch over the direction of rotation.

5. Preparation

5.1 Treatment instructions/warnings
To avoid damage, do not use metal brushes or cleaning sponges.
Only use cleaning and disinfectant solutions with a pH value of between 4.5 and 10. Follow the manufacturer's instructions (e.g., intended purpose, dosage, exposure period and replacement of the solution).
The ratchet is not sterile when delivered and must be cleaned and sterilised before it is used.
When using several torque ratchets, do not interchange the individual parts. Each individual part belongs to the respective instrument.
Damaged products must go through the reprocessing process before being returned for repair.

5.2 Restriction regarding repreparation
The end of the product's service life is normally determined by wear and damage caused during use and by incorrect handling.

5.3 Preparations for cleaning
For cleaning the torque can be disassembled without using any tool. Please unscrew the screw completely. Then, the entire pawl can be taken out.



Clean the parts under cold running water using a soft brush to remove all visible soiling. Ensure that all openings and cavities are thoroughly rinsed. Do not allow blood and other soiling to dry on.

5.4 Cleaning and disinfection: Manual
Ultrasonic cleaning bath: Place the parts into a wire basket and ensure that the parts do not touch, in order to avoid acoustic shadows. Clean for 3 minutes in an ultrasonic cleaning bath (35-40 kHz) at a temperature of 40°-50°C with an enzymatic cleaning solution. Ensure that the parts are completely immersed in the water, without the formation of any bubbles. Rinse with clear, cold water; if possible, use deionised water. Dry the parts with a lint-free cloth and blow dry with compressed air.

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Securely apply the cleaned ratchet parts to the carrier. Do not overload the carrier. Start the program. After rinsing, chemical cleaning starts at 40°-60°C. Residues from the cleaning process must be reliably removed in the subsequent rinsing phase. Avoid damage to the material from neutralising reagents. Thermal disinfection is achieved at 90°-95°C. The subsequent treatment with deionised water is followed by adequate drying. Remove the ratchet parts from the device immediately after the program ends.

5.6 Maintenance, inspection and testing
Allow the parts to cool to room temperature and visually inspect them for residues of proteins and other soiling. If necessary, repeat the preparation steps.
Lightly lubricate the areas marked with ♦ using contra-angle handpiece oil. Assemble ratchet and carry out functional test.

5.7 Sterilisation packaging
Place the ratchet into packaging suitable for sterilisation according to ISO 11607 and EN 868. The bag must be large enough for the instrument. Closures must not be under tension.

5.8 Sterilisation
Method: Fractionated pre-vacuum process in accordance with ISO 17665
Temperature: heating to 134°C,
Pressure: 3 pre-vacuum phases with a minimum pressure of 60 millibars
Holding period: 5 minutes
Drying time: at least 10 minutes
After sterilisation, inspect the sterile packaging for damage and check sterilisation indicators.

5.9 Place of use
Immediately after use, the products must put in cold water (<40 ° C). Use no hot water (> 40 ° C) or cleaning agents, as this may cause fixation of residues on the product (risk of protein coagulation (denaturation)), which can affect the success of the subsequent processing steps.

6. Storage
Store the ratchet at a moderate temperature, and in a dry, dust-free, well-ventilated place, in which there is no corrosive steam.

7. Shipping
The ratchet must be cleaned and sterilised before shipping, otherwise the product will be returned.

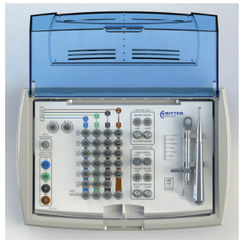
CAUTION

„CAUTION: please make sure that the screw for fixation of the "direction turning grip" is entirely closed and tightned till the end. If this is not applicable the pawl will not grip the tool properly and tools may fall out or the ratchet head will turn through."

Instructions for use - Surgical Kit System

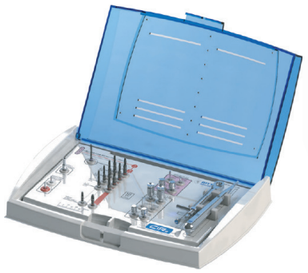
Class IIa (CE1023) categorie:
Professional Kit: RIBEU-PE
Professional Kit USA Narrow Line: NL-RIBUS-PE
Professional Kit USA: RIBUS-PE
Starter Kit: RIBUS-SE
Guided Kit: GSKIT

Class I (CE) categorie:
Prosthetic Kit: RIB-PROS



RIBUS-PE

RIBEU-PE



NL-RIBUS-PE

RIB-PROS

GSKIT

RIBUS-SE

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

ITEM NO. / TOOL DRILL	DESCRIPTION	FUNCTION - how to work / used by
CDEP drills / GSD 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 GMMIO /NL-GMMIO	Motor Mount for Implant with ball friction or ring 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 /GRDIO GRDIS/NL-GRDIO/NLGRDIS	Implant driver with head for ratchet normal and narrow line	For insertion of implant with ratchet/ dentist
HHDA / Long and short	Hand Hex driver for abutments	for fixing / assembling abutments by hand torque, Laboratory and dentist
MMA / Long and short	Motor Mount for abutments	for fixing / assembling abutments by motor / Laboratory and dentist
DEX	Drill extender	extends the length, used with all items with SD coupling head for handpiece / Laboratory and dentist
CD drills	Hard bone drills, bone profiler	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	Ratchet / with torque measurement	for fixing all items with ratchet head / Laboratory and dentist
IDP	Implant Deep Probe	for improving the depth of the drilled cavity
TP	Tissue Punch	for removing tissue in a fixed diameter
GPIN	Guided Pin	Fixating of a template

Correlation of tools Purpose and use of

CAUTION

For torque ratchet or motors:
Max. loading with hardened RA-shanks: 80 Ncm
Max. loading with non hardened RA-shanks: 40 Ncm

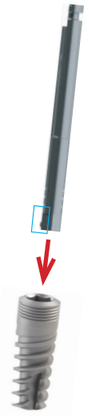
Implants

Motor Mount for Implant Hex 2.0

NL-GMMIO
NL-MMIB

Motor Mount for Implant Hex 2.43

GMMIO
MMIB

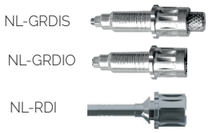


MMIB, GMMIO,Motormount with ball or ring friction hold and SD-coupling plug for catching and inserting the implant with a contra angled handpiece / motor.

Implant ratchet drivers with heads for the use with the ratchets.

Implants

Ratchet Driver for Implant Hex 2.0



NL-GRDIS
NL-GRDIO
NL-RDI

Ratchet Driver for Implant Hex 2.43

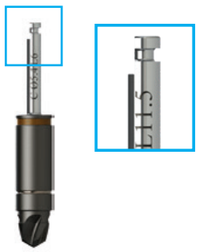
GRDIS
GRDIO
RDI

Screw Driver for Implant NL-Hex-2.0
NL-SDH

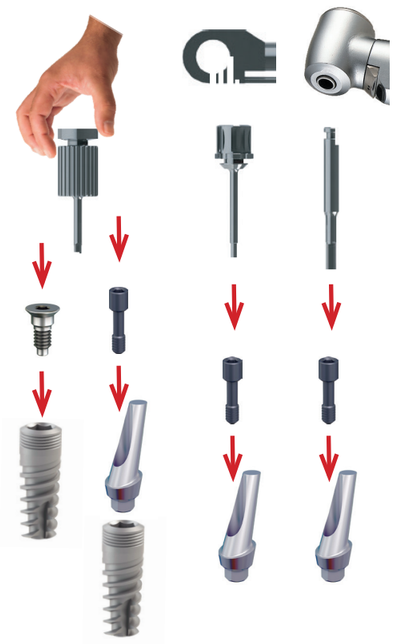
Drills

Drill extension DEX/DIX to extend the drills.

Drill Extender for external irrigation drills
DEX



Abutment Ratchet drivers with heads for the use with the ratchet, by hand or with SD-coupling for the use with a contra angled handpiece / motor. Fixation of Abutment and CSI coverscrews.



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

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

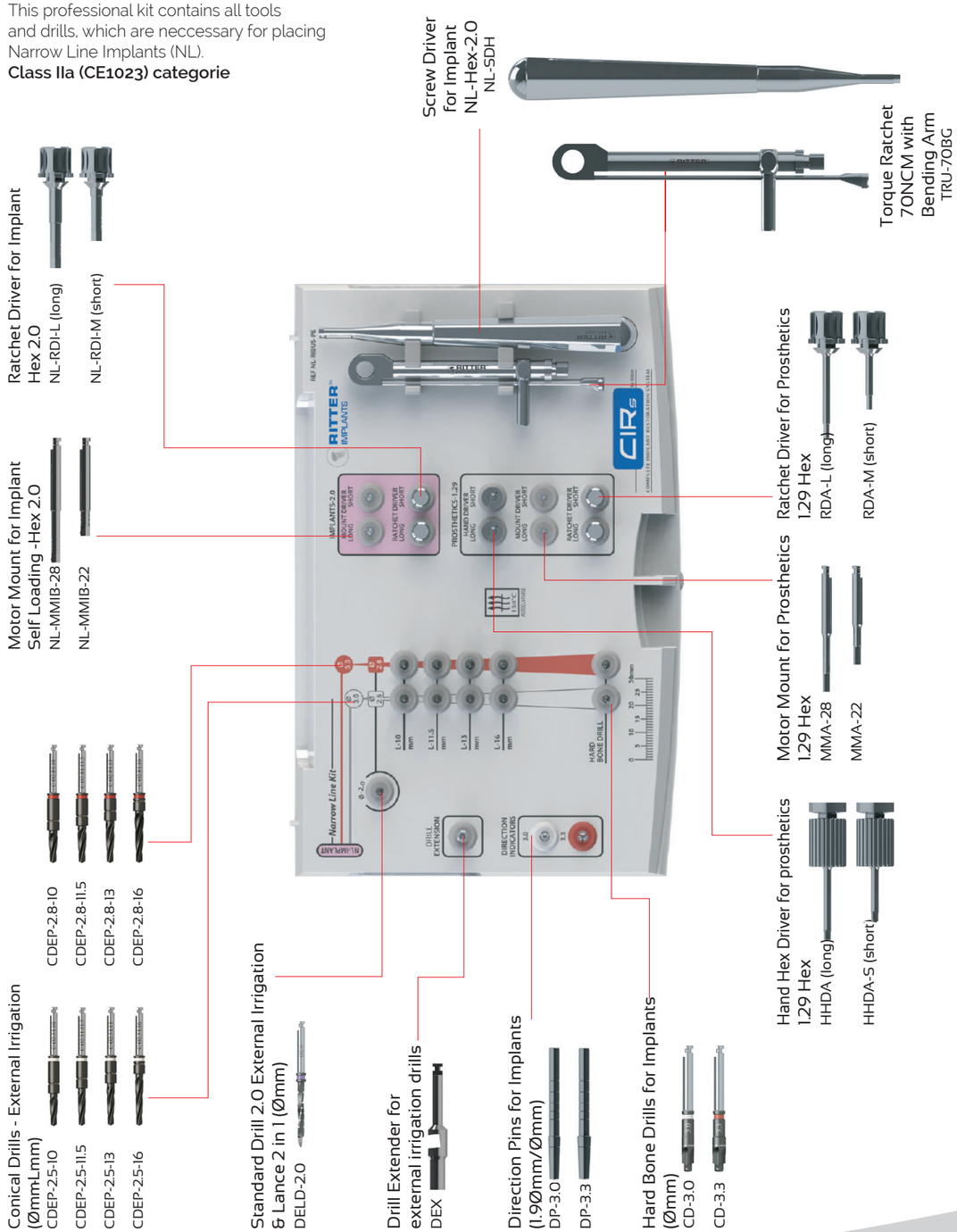
Ratchet Driver for Prosthetics
1.29 Hex
RDA-L (long)
RDA-M (short)

Abutments and screws

Instructions for use - Surgical Kit System

Professional Kit USA Narrow Line: NL-RIBUS-PE

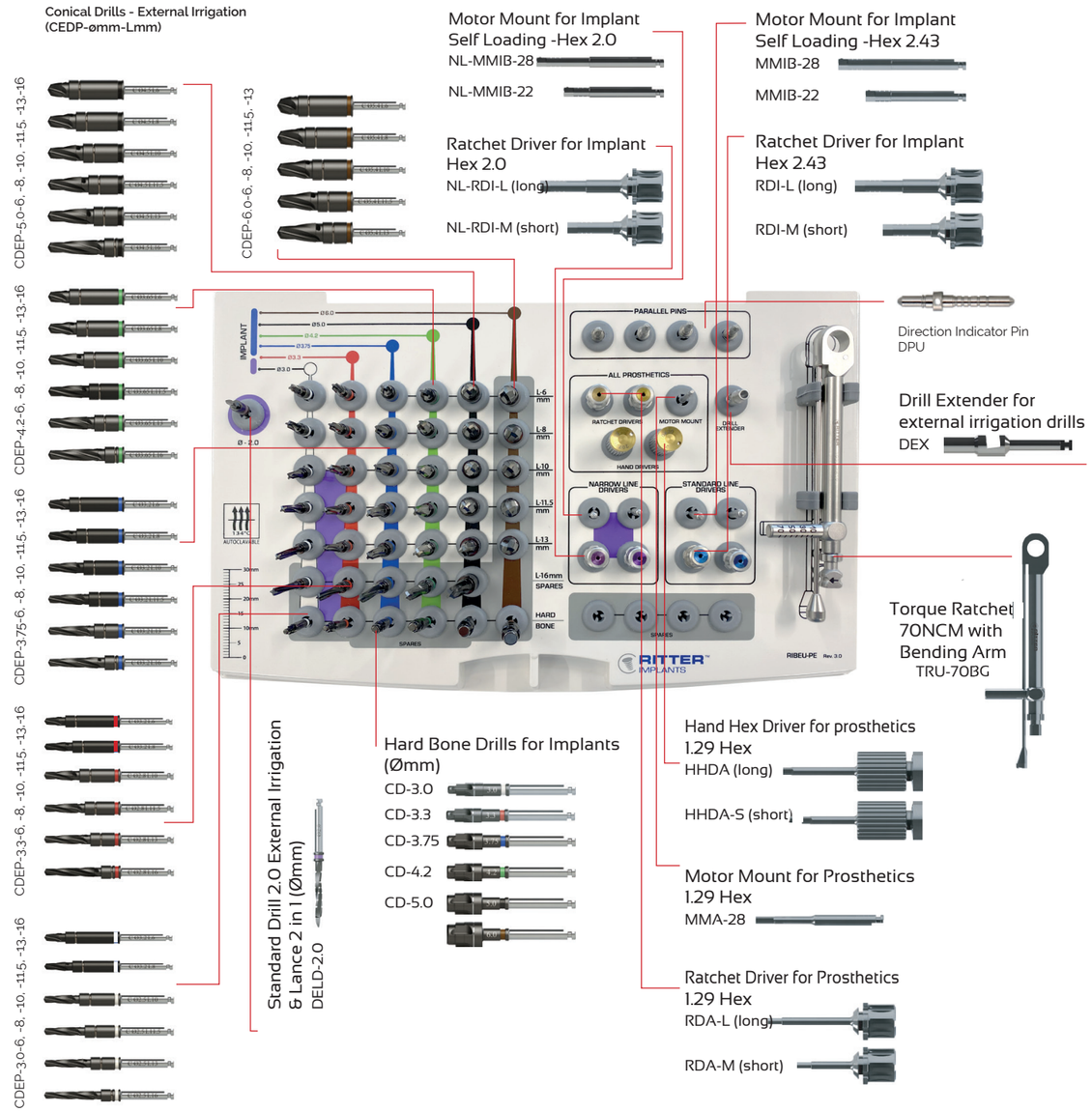
This professional kit contains all tools and drills, which are neccessary for placing Narrow Line Implants (NL).
Class IIa (CE1023) categorie



Instructions for use - Surgical Kit System

Professional Kit: RIBEU-PE

This professional kit contains all tools and drills, which are neccessary for placing Implants with all diameters, incl. Narrow Line (NL).
Class IIa (CE1023) categorie



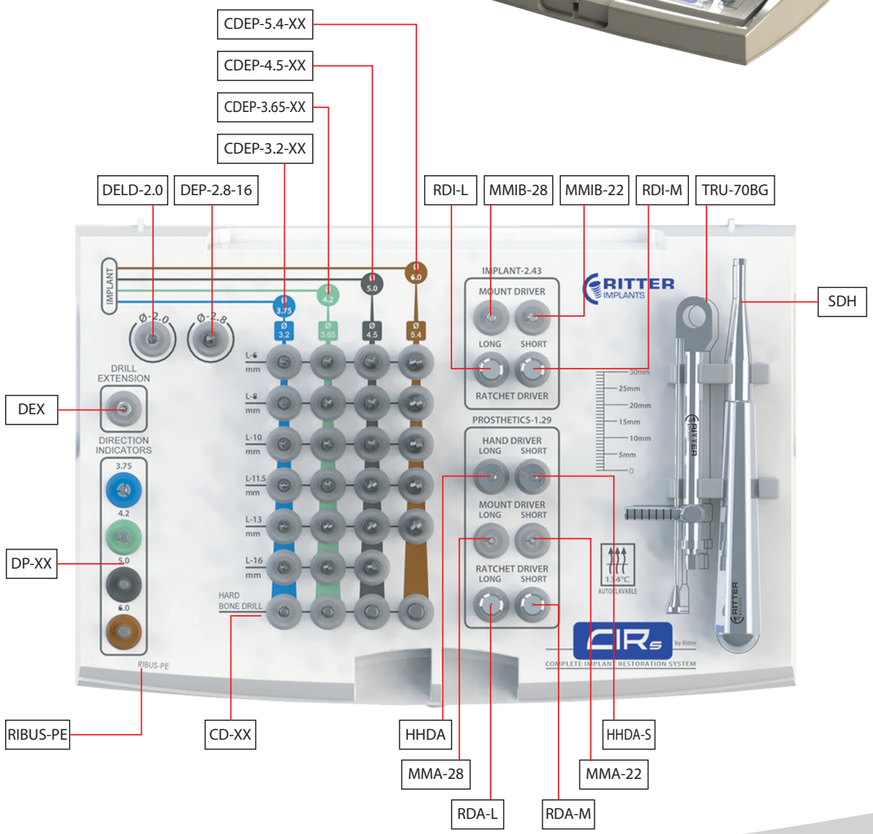
Instructions for use - Surgical Kit System

Professional Kit USA: RIBUS-PE

This professional kit contains all tools
and drills, which are neccessary for placing
normal platform Implants ø 3.75- 6 mm
Class IIa (CE1023) categorie

Surgical Kit CIR's System - Complete set
Professional / External Irrigation Drills

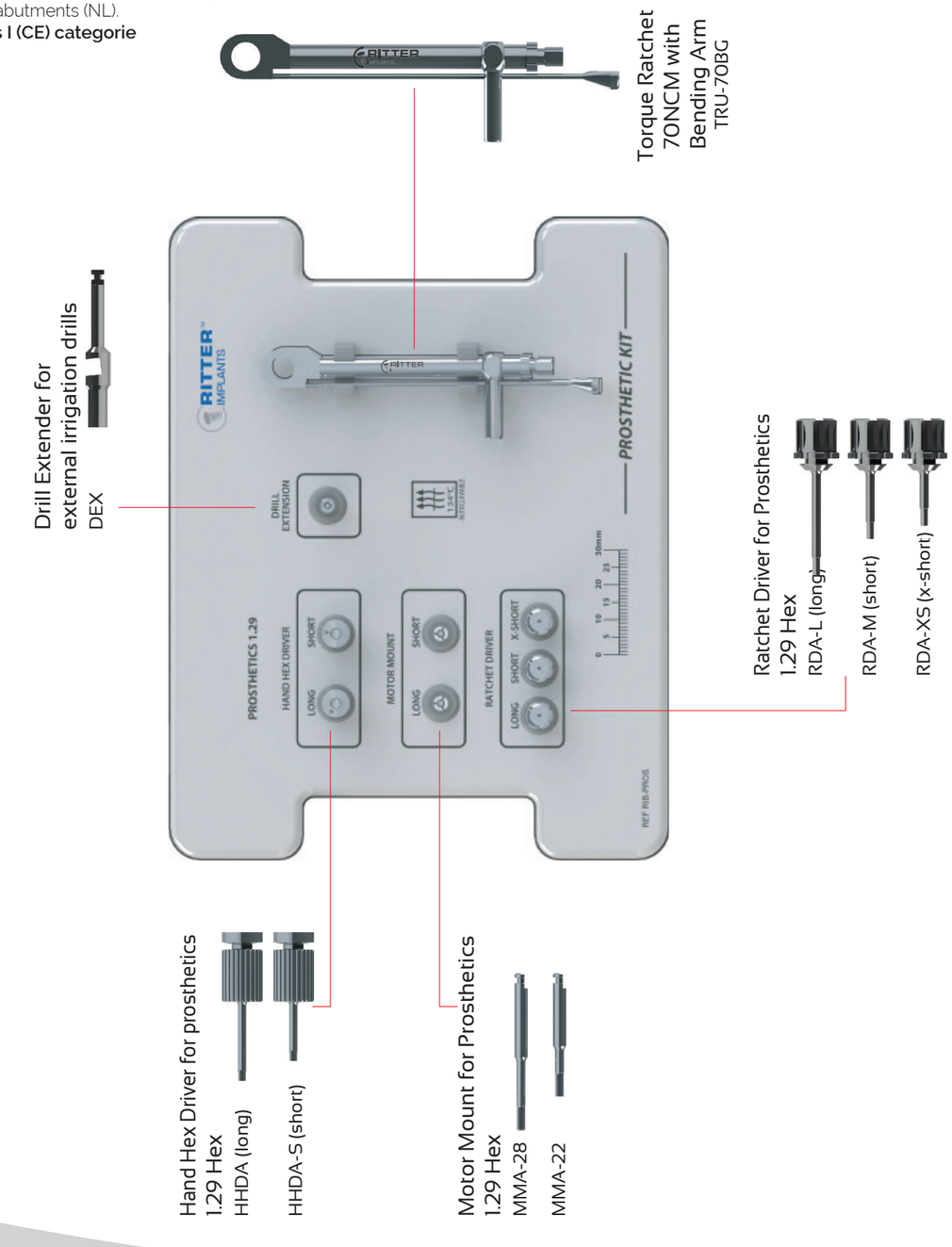
REF RIBUS-PE



Instructions for use - Surgical Kit System

Prosthetic Kit: RIB-PROS

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



Instructions for use - Surgical Kit System

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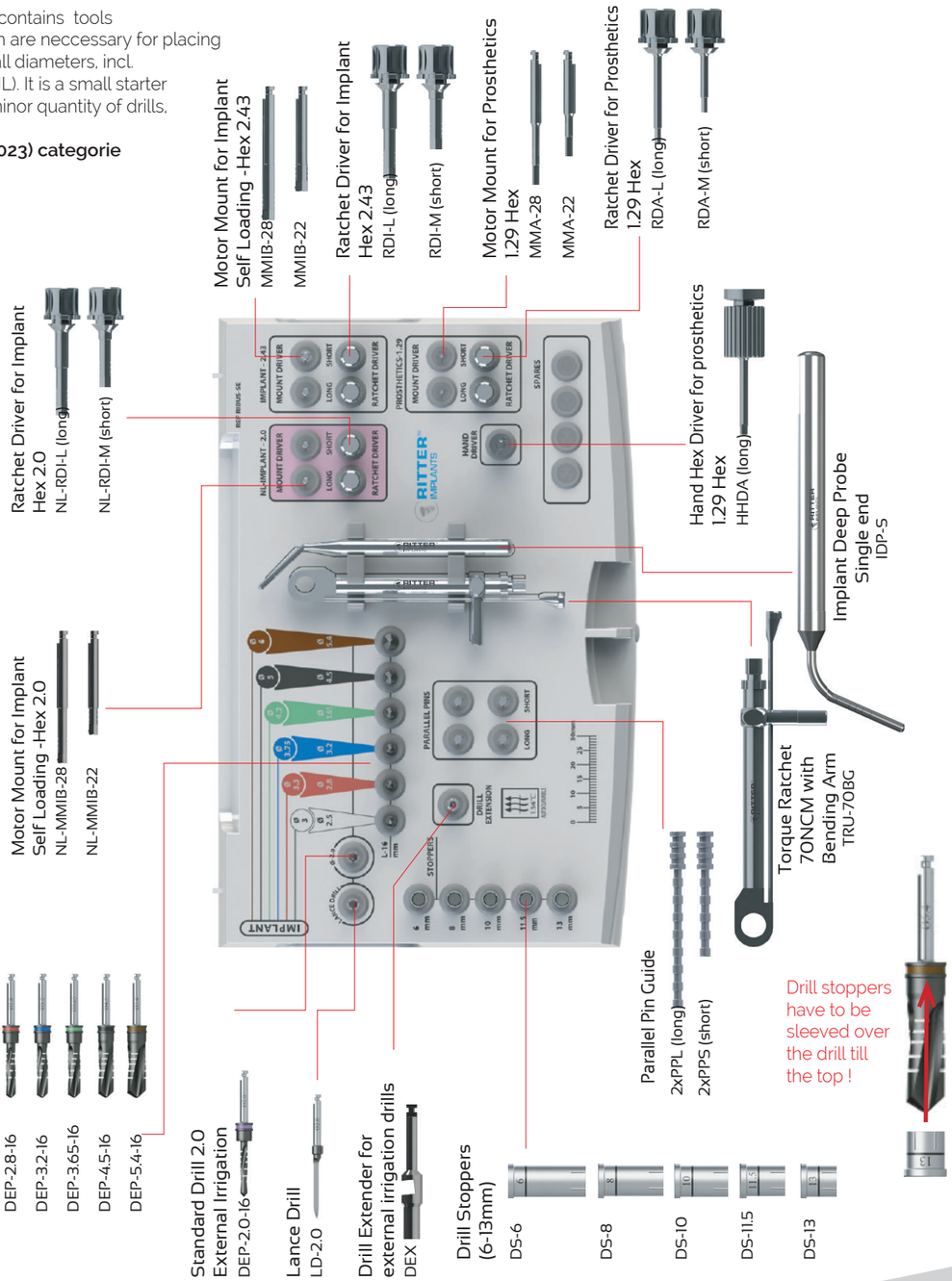
Starter Kit: RIBUS-SE

This starter kit contains tools and drills which are neccessary for placing Implants with all diameters, incl. Narrow Line (NL). It is a small starter solution with minor quantity of drills, non conical.
Class IIa (CE1023) categorie



Instructions for use - Surgical Kit System

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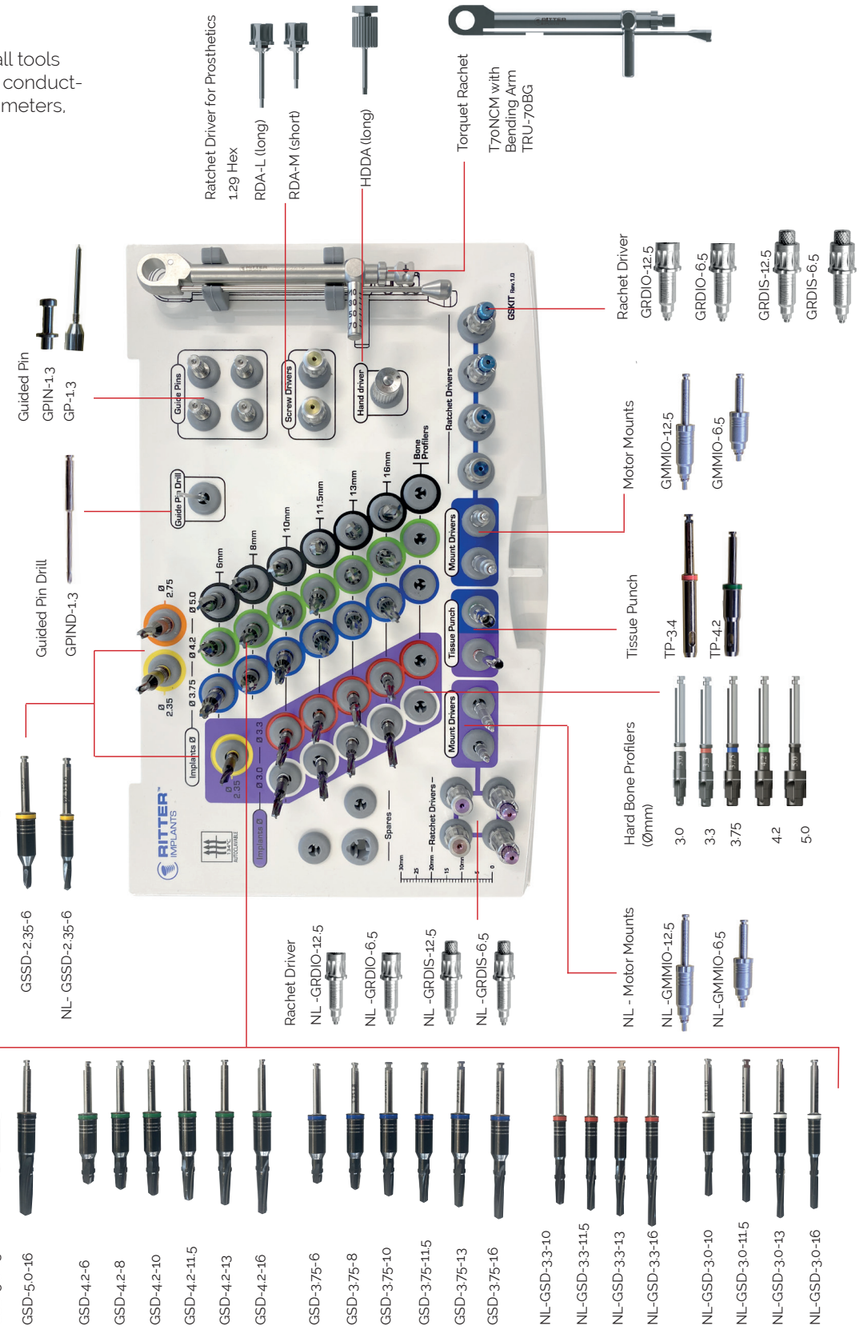
Guided Kit: GSKIT

This guided system it contains all tools and drills that are necessary for conducting a guided surgery with all diameters, including Narrow Line
Class IIa (CE1023) category



Use of Starter Kit with straight - non conical - drills
The Starter Kit is equipped with non conicals drills DEP instead of conical drills CDEP, which are placed in the Professional Kit.
It is recommended to use the Lance Drill LD or the DEO 2.0 drill prior to the next or final drill.

Table B: QSI and SB/LA Spiral Implants -SNAP-						
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 DEP	LD / DEP 2.0	1	1	2	3	4
Bit width DEP	2.0	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

CLEANING/ DISINFECTION/ STERILIZATION INFORMATION (prior and after use):
Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.
Use the following guidelines for cleaning products as drills, instruments and components: Disassemble multi-piece components, if applicable.
MANUAL CLEANING:
Before use, soak the drills/ tools in a mild, pH-neutral enzymatic detergent for 2.5 minutes or until cleaning can performed.
While the parts are submersed, a nylon brush is used to clean the surface of the drills/ tools.
After the immersion period, tools/ drills are removed from the enzyme solution and are rinsed thoroughly under hard stream of tap water for 1 minute. Avoid water with high concentration of chlorine.
Tools/ drills are left to complete air dry for 2 minutes.
MECHANICAL CLEANING/ AUTOMATED CLEANING:
An automated washer is filled, with mild, pH-neutral enzymatic detergent.
The tools/ drills are inserted into the Automated washer.
After the mechanical cleaning, tools/ drills are removed from the washer.
Tools/ drills are left to complete air dry for 2 minutes.
MANUAL DISINFECTION:
Tools/ drills are soaked in 70% Isopropyl Alcohol for 2.5 minutes.
While the parts are submersed, a bristle nylon brush is used to clean the surface of the tools/ drills.
After the immersion period, the tools/ drills are removed from the Isopropyl Alcohol and thoroughly disinfected using clean, lint-free cloth- moistened with the cleaner disinfectant.
Tools/ drills are left to complete air dry for 2 minutes.
STERILIZATION:
1. Wrap the tools/ drills or place in surgical kits for sterilization with wraps washed in pH-neutral detergents or disinfectants.
2. Sterilize the tools/ drills by steam according to the autoclave's instructions.
134˚C/273˚F for 6 minutes followed by a 30 minutes dry cycle. Distilled water should be used in order to avoid surface stains.
Make sure before use that the elements, inside the autoclave, are not rusted.
Exceeding of the 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 shoud be considered. Chemclave sterilization is NOT recommended for any Ritter Implants Dental products.

Tools, drills and parts individually pouched or placed in surgical kit	**Cycle Type**	**Temperature**	**Exposure time in Minutes**	**Drying Time in Minutes**
	Gravity (steam)	134˚C/ 273˚F	6	30

Symbol	**Symbol Title**	**Explanatory Text**	**Standard, Reference Number**
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1 Reference #5.2.4 FDA Recognition # 5-117
Single Use	Do not re-use	Indicates that the medical device should not be used a second time	ISO 15223-1 Reference #5.4.2 FDA Recognition # 5-117
CAUTION	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions	ISO 15223-1 Reference #5.4.4 FDA Recognition # 5-117
www.ritterimplants.com/IFU	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Reference #5.4.3 FDA Recognition # 5-117
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	ISO 15223-1 Reference #5.2.8 FDA Recognition # 5-117
	Use-by Date	Indicates the date after which the medical device is not to be used	ISO 15223-1 Reference #5.1.4 FDA Recognition # 5-117
REF	Catalogue Number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1 Reference #5.1.6 FDA Recognition # 5-117
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	SO 15223-1 Reference #5.1.5 FDA Recognition # 5-117
STERILIZE	Do not Re-sterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1 Reference #5.2.6 FDA Recognition # 5-117
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 Reference #5.1.1 FDA Recognition # 5-117
CE 1023	CE Mark / with Notified Body Reference ####	Signifies European conformity (CE) mark / Indicates conformity of products where the notified body performed conformity assessment. Notified body reference # is displayed	NA
Rx only	Prescription Statement	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911 FDA Reference # 2016-13989
NON STERILE	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1 Reference #5.2.7 FDA Recognition # 5-117
10°C/ 50°F 23°C/ 73.4°F	Temperature limit, Storage condition 10˚C-23˚C/ 50˚F-73.4˚F	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 Reference #5.3.7 FDA Recognition # 5-117
20% 75%	Humidity limitation, Storage condition 20-75%	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1 Reference #5.3.8 FDA Recognition # 5-117
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1 Reference #5.2.11
MD	Medical device	Indicates the item is a medical device	ISO 15223-1 Reference #5.7.7

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