Operating manual





New technique for the preparation of implant beds



Soft Dilators, the new progressive instruments for the conformation of the implant socket

New Technique for the preparation of implant beds

SOFT DILATORS INDICATIONS

1. PROGRESSIVE BONE EXPANSION

• Allows the placement of implants in severely resorbed and thin alveolar ridges, through a **progressive bone expansion** of the alveolar ridge of the upper or lower jaw. It facilitates the placement of implants associated with simultaneous bone augmentation techniques and reduces the need for preliminary bone thickness augmentation procedures before the placement of implants.

2. PROGRESSIVE BONE CONDENSATION

• Permits to increase the primary stability of the implants in situations of low bone density through a **progressive bone condensation** of the alveolar ridge of the maxilla or the mandible.

3. VERTICAL BONE EXPANSION

• It is also able to realize a simultaneous **vertical bone expansion** in order to achieve a trans-alveolar sinus floor elevation according to Summers technique.

Generally, most implant sites can be prepared using the Soft Dilating System. The SDS may therefore be considered as a primary technique for bone preparation in Implantology.



SDS DESIGN AND OPERATING PRINCIPLES

The Soft Dilating System mainly consists of a telescopic handle with a tool attachment head (Fig. 1) and a series of Dilators (Fig. 2).

Fig. 1

Fig. 3

The diameter of the Dilators ranges from 2.00 mm to 5.50 mm, corresponding to the preparation diameters of all actual implant systems.

The sequence of the

increments (Fig. 4):

to the diameter of the

Soft Dilators have a cylindrical-conical profile; conical from the apex to the 8 mm mark, then cylindrical (Fig. 3).

Soft Dilating System

@2.75 Ø3.00 Ø3.15 Ø3.25 Soft Dilators is designed with overlapping diameters the diameter of the apex of each Dilator corresponds

cylindrical part of the previous Dilator.

Fig. 4

The cross-section shows a polygonal form with concavities and Fig. 5 smoothed edges. (Fig. 5). in reverse rotation. (Fig. 6). apex of the Dilator Fig.7 (Drilling Security System) (Fig. 7).

The only cutting parts are the apex and a single axial cutting edge, active only

axial cutting edge

Fia. 6

Soft Dilators are provided with depth laser marking and a microthreaded shank, permitting the coupling of the instrument with screwed micrometric stop devices DSS

Fig. 2

SDS USE PROCEDURE

The handling technique consists in an initial pilot drilling followed by the use of the series of Dilators in sequence.

For crestal expansion with the SDS, it is generally necessary to open a traditional gingival flap. Contrariwise, in cases where the goal is a condensation of the alveolar bone, it is possible to proceed even without a flap. The manipulation of the instruments is the same in both cases..

Pilot drilling (Fig. 8):

The **DSS(*)** pilot drill of the SDS Kit has a 1.75 mm diameter. It should preferably be used with an implantology handpiece at a rotation speed of 800 -1000 rpm.

The pilot drilling should be 0.5 - 1.0 mm deeper in order to facilitate the full insertion of the subsequent instruments. Care should be taken to maintain an adequate safety distance to prevent any damage to adjacent structures.

Dilatation (Fig. 9):

Use the series of Dilators in sequence, making **pressure-rotation movements** with the SDS handle (*watch the video clip available at www.arsline.com/sds*).

These alternate side rotations permit the preparation of the implant bed by progressive dilatation of the bone ridge and achieve a seating with a circular cross-section in a non-aggressive way (**Fig. 10**).





*DSS (Drilling Security System): System of universal drills for implantology also patented by Arsline, provided with security devices with screwed stops allowing precision micrometric setting and immediate adjustment (*see voir www.arsline.com/dss*).





Use of the SDS Handle:

Take the Handle (**Fig. 11**) and check that the clamp (**A**) which blocks the sliding of the counterweight (**B**) correctly retain the hexagonal bar (**C**).





Push the button (**D**, **Fig. 12**), insert the dilator and, by rotating, find its correct seating position.

Remarks:

- Release the button and check the correct attachment of the dilator to the head of the handle (**E, Fig. 11**) by trying to pull it out.

The verification of this correct attachment is necessary to avoid damage to the retaining mechanism during its use.

Attention: during instrument removal, if the dilator is not fully released from its seating position, do not force, so as not to damage the components of the head.

- The insertion of the Dilator automatically sets the position of the **axial cutting edge** (**Fig. 13**) on the **opposite side of the button** (**D**, **Fig. 14**). This edge limits the risk of instrument drift in the direction of the weakest wall of the implant bed.

necessary, it is also possible to use the "**Cortical Drill**" (**Fig. 26, Page 11**) to avoid this drift.



To ensure the necessary pressure and stabilize the working axis of the Dilator, it is possible to use the **semi-sphere** of the head of the handle (**A**, Fig. 15) as a point of support.

The sequential use of the Dilators with increasing diameter permits the progressive preparation of the implant seat by bone expansion and/or condensation.

It is possible to engage the sliding of the telescopic handle (**B**, **Fig. 11**, **Page 5**) by unscrewing the blocking clamp (**C**, **Fig. 11**, **Page 5**).



Using its weight it can be used as an extractor in order to withdraw an instrument from its bone seat in a perfectly axial manner.

(see video clip at www.arsline.com/SDS)

The weight of the SDS Handle also permits the application of slight blows on the last dilator which realize a **vertical bone Expansion** on lateral maxillary sites (trans-alveolar sinus floor elevation according to Summers).

The dilators can also be used for the placement of conical implants as long as the preparation is adapted by considering the neck and apex diameters, as well as the degree of taper, of the implant.

As a general rule, the procedure consists of not using the last dilator and perhaps not even the second to last one to the extreme bottom of the preparation.

Before placing the implant, it is recommended to check the dimensions of the preparation by using the corresponding gauge.

Manual bone dilatation by the Soft Dilating System does not require irrigation.

SYSTEM ADVANTAGES

The rounded angles and the concavities of the instruments permit the carrying out of the technique using only low force intensities. The unique design of the SDS dilators, with a concave polygonal cross-section, gives the manipulation its specific **"soft"** characteristic for bone expansion and condensation.

During the insertion of the instrument, only **low pressures** are applied, as only blunt edges enter into contact with the bone and as the rotation brings about the dilation without force.

The progressive use of increasing diameters gives continuity to the dilatation until the desired diameter is obtained.

These characteristics permit a "soft" technique, avoiding the use of the mallet and protecting the bone tissue.

This "soft" dilatation limits the risk of dehiscence of the cortical plate and bone fractures. Compared with that of Soft Dilators, the greater contact surface of the circular cross-section of all the *classic osteotomes* implies a much greater pressure on the surrounding bone, imposing the use of a mallet.

Compared to *conical screw dilators*, Soft Dilators offer a low traumatic technique for thin cortical plates and the possibility of a better control of the preparation axis.

Compared to traditional drillings, Soft Dilators protect the bone tissue which is not carved but centrifugally dilated.

REMARKS

- The Ø 1.75 mm Pilot Drill is provided with a **punch** (**Fig. 16**); therefore, there is no need to use a spherical cutter initially on the alveolar crest to start the drill hole.

The Pilot Drill is also provided with micro threading which permits coupling with DSS Stops. This threading permits a micrometric adjustment of the stop and a precise and safe length control of the desired drilling depth.

- The mounting of the stop is carried out by inserting it along the shank of the drill and screwing it in the direction opposite to that of the drilling (**Fig. 18, 19 and 20**).

The stop is provided with a **friction ring** (**Fig. 17**). The adjustment of the stopping position is easy when the "**Drill Knob**" (**Fig. 21**) is used or by attaching the drill to the **handpiece** (**Fig. 22**). Thanks to this it is possible to realize a quick positioning of the stop by a screwing of the drill.

- Make preliminary adjustment of the stop position by screwing it to a level corresponding to the desired implant length, referring to the laser marks (6, 8, 10 -12, 14 mm, **Fig. 18**), or by using a ruler or a caliper.







TIPS AND TRICS

1. If the pilot drilling is localized between cortical plates of different strengths (typically the palatal or lingual cortical plate is denser and thicker than the vestibular plate), place the pilot drill punch **slightly closer** to the denser cortical (**Fig. 23**).

During drilling, **press** transversally the drill against this latter cortical (**Fig. 24**), in order to avoid drift of the pilot drilling toward the weaker cortical.

2. During the pilot drilling and the ridge expansion it is possible to hold the bone ridge **between the thumb and index finger** (Fig. 25). This allows to perceive the direction of drilling and any tendency to drift and also helps maintain the integrity of the cortical walls.

3. It is relatively rare that the drilling axis is perfectly orthogonal to the ridge table. It will thus be necessary to make a **over-correction of the Stop position** (i.e. a slight screw-back of the stop with respect to the chosen drill length) in order that early contact of the outside edge of the stop with the alveolar crest does not impede the full insertion of the drill to the desired depth (**Fig. 26**).

4. The Dilators have a **cutting apex** (**Fig. 27**) which permits each instrument to reach the desired depth.

Avoid any accumulation of apical bone chips which could cause a shortening of the implant seating. If necessary, **rinse** the implant site with physiological serum during the dilation procedure.

5. The Dilators are cylindrical-conical (tapered from level 8 mm to the apex) (**Fig. 3, Page 3**); the apical diameter of the preparation is therefore slightly **narrower** than the cervical diameter.

Before the insertion of an implant, if the bone is very dense or if it has been highly condensed, it is possible to make another pass with the final drill (very slowly, eventually even by hand using the Drill Knob).











Soft Dilating System

Attention: when being used in the mouth, the Drill Knob can slip out of the fingers; therefore, it is recommended to attach it with dental floss through its mounting hole.

6. If the implant system foresees it, a thread tap can also be used.

This is especially recommended in the case of extensive condensation, in order to avoid excessive periapical compression and bone necrosis.

7. In case of low bone density, it is possible to perform a discontinuous dilation, by using every second dilator diameter
(Fig. 28).

This procedure is not recommended for the final diameters, as a progressive dilatation is more precise.



8. The dilators are available in numerous diameters, which permits the adaptation of the final diameter of the seating to various implants.

9. dense bone, dilation to achieve bone condensation is not indicated.

THE SDS HANDPIECE: (not included in SDS Kits)

\land Remarks:

The connection of the Soft Dilators is generally not compatible with standard implantology handpieces, because it is not possible to hook the locking lever or button. The attachment system of the SDS Handpiece is in accordance with the coupling standard Type E (ISO 3964) for instruments 2.35 mm in diameter. The length of the instrument shank is 12.5 mm minimum.

It is not recommended to use handpieces which generate excessively high rotation speeds and inadequate torque.

The SDS Handpiece (**Fig. 29**) is a tool that easily allows the use of Dilators in rear areas that are difficult to reach with the SDS Handle. Its reduction of 1:256 produces a very high torque and a very low rotation speed.

Dilators can only be used at the maximum speed of 15 rpm!



When working in normal clockwise rotation with the SDS Handpiece, the Soft Dilator's cutting edge is not active (active only in counter clockwise rotation).

Therefore, it may be necessary to apply strong pressure to the head of the Handpiece in order to obtain sufficient penetration of the instrument.

In order to avoid overheating, it is recommended to work intermittently and to irrigate abundantly.

The SDS Handpiece comes with a set of DSS Stops, one for each Dilator (Posterior Kit). These may be used on DSS drills of the same diameter as the SDS

UTILISATION OF SDS HANDPIECE AND SDS STOPS

SDS Handpiece:

Use with motors having a maximum speed of 40.000 rpm.

Mounting of the rotating instrument in the handpiece:

- Open the lever.

- Insert the instrument by orienting it on the driving flat.
- Lock the lever.
- Apply a slight traction on the instrument to make sure that it is mounted correctly.

DSS Stops:

Mounted on the Dilators, the DSS Stops permit:

- 1. that the pressure applied does not accidentally cause excessive penetration.
- 2. stopping of the penetration of the Dilator at the desired depth.
- 3. that the insertion of the Dilator be complete,

4. that an automatic extraction of the Dilator takes place at the end of the shank (when the Stop encounters the cortical plate).

NEVER EXCEED A TORQUE OF 40 N.CM WITH THE SDS HANDPIECE!

It is, therefore, recommended to use a motor equipped with torque control.

Remarks:

The SDS Handpiece is not recommended for drilling in extremely dense bone, as its maximum speed of 160 rpm (with a motor at 40,000 rpm) is not sufficient for drill penetration.

. Pilot drilling is generally carried out with a traditional implantology handpiece using the technique described above.

Due to the very slow rotation of the SDS Handpiece, the Stops must be used without Friction (Fig. 17, Page 7), contrary to the DSS Pilot Drill.

Handling of Soft Dilators with the SDS Handpiece:

- Insérer le Dilatateur avec la guillotine de blocage (Fig.30) ouverte et s'assurer que l'instrument soit inséré à fond. - Refermer la quillotine et vérifier que le Dilatateur

soit parfaitement retenu par celle-ci.

Dilatation:

- Insert the Dilator mounted on the Handpiece and press axially until the complete insertion of the Dilator at the speed of **15 rpm**.

- It is possible to **press** with a finger of the opposite hand on the head of the Handpiece to aid the penetration of the Dilator and to maintain the chosen working axis.

- Continue the dilatation process with the Soft Dilators of the subsequent diameters until the formation of a suitable seat for the placement of the implant.

Action of the DSS Stop:

Once the predetermined depth has been attained, the Stop will cause the removal of the instrument from its bony seating as it is screwed to the Dilator in the opposite direction with respect to the direction of rotation on the Handpiece (DSS patent).

Remarks:

- During the release of the SDS Dilator (begun by the DSS), assist the extraction of the instrument by **pulling slightly** in the opposite direction.

In the case of low bone density, it is possible to finish the site preparation by using a Dilator of **one lesser diameter** than that of the implant to be used.

- To correct the axial drift which could occur during the preparation, use the "Cortical Drill" (Fig. 31, Page 11) a traditional handpiece.



- **DSS Stops** sare also helpful when the Dilators are used with the SDS Handle; therefore, we advise always leaving them premounted on each Dilator before the surgery.

- The **Friction Ring (Fig. 17, Page 7**) which is inserted behind the Stop of the Pilot Drill, should be changed approximately every 10 uses as it will no longer be able to guarantee sufficient stability of the stop during the drill rotation.

General risks:

-- This product is intended for use by suitably trained medical professionals.

- Before using the Handpiece, the user must check that it is operating correctly.

- If the Handpiece should receive a blow, check the general condition of the device and of the installed rotary instrument.

- In case of doubt about the use of the Handpiece, contact the local distributor or product manufacturer.

- The manufacturer cannot be held responsible if any alteration or additions have been made to the product without their prior authorisation.

Infection risks:

- Disinfect and sterilize before the first use and after each successive use.

- Drain the irrigation pipes before each sterilization.

Electrical risks:

- The use of the Handpiece is authorized only with low-voltage medical units in accordance with the directives related to medical devices (93/42/CEE).

Mechanical risks:

- Check that the rotary instrument is held correctly after each replacement.

- Never insert the handpiece into, or remove it from, a motor during rotation.

- Never handle the rotary instrument during its work.

- Never activate the tool change system during use of the Handpiece or before the rotary instrument has come to a complete stop.

- Never remove the rotary instrument if it is not fully unlocked from the coupling slot.

ACCESSOIRES (not included in SDS Kits)

Instructions for use:

The Cortical Drill - Ø 2.2mm (Fig. 31) may be used:

a. For remodelling of the bone ridge.

b. To help the function of the axial cutting edge of the dilators, to limit its drift with respect to the chosen axis.

c. To correct a wrong initial drilling direction.

d. To remove remaining fibrous tissue from the bone crest before the placement of graft material or to scrape out remaining periodontal ligament before the placement of an immediate implant.

The **Crestal Shaper** (**Fig. 32**) is a drill with concave walls used for reshaping edges and irregularities of the bone ridge and to achieve flattening if necessary. It should be used before the implant placement with a moderately fast handpiece and abundant irrigation.



The **Crestal Planer** Ø4.8 and Ø6.3 mm (**Fig. 33**, **34**) flattens the peripheral bone ridge at the implant site. Making it orthogonal to the drilling axis, they are useful to avoid asymmetric countersinks of implant's neck or to avoid that a portion of the treated surface of the implant presents a lack of bone coverage. They are used after the pilot drilling with a moderately fast handpiece and abundant irrigation.

The **Pins Series1** (**Fig. 35**) is a series of cylindricalconical gauges that, in combination with the Dilators, permits verification of the diameter and depth at any stage of the dilatation procedure. In order to check the suitability of the final hole diameter and depth for the chosen implant placement, verify contrariwise with the gauge of the implant system corresponding to the chosen implant.

The Ø 1.75 Pin (Fig. 36) is a gauge which permits verification of the depth and axis precision of the pilot drilling as well as an radiographic check. Inserted after a pilot drilling, it may be used as optical landmark to parallelize drillings for further implants.



Fig. 36

MAINTENANCE

Dilators – Stops – Cutting instruments:

The strict respecting of the rules of maintenance is essential to preserve sharpness and a proper functioning of the instruments.

Unsuitable or insufficient care of stainless steel instruments can damage them in a very short time.

1. Never allow residue (blood, secretion or tissue) to dry on the instruments. It is recommended to immerse the instruments in demineralised water after use and in disinfectant after the surgery.

2. Instruments consisting of several parts (i.e.: drills, dilators, DSS stops, friction rings) must be first disassembled, then cleaned and disinfected and then reassembled and sterilized.
3. Any incrustations must be cleaned off thoroughly with only nylon brushes. Clean hollow

spaces especially well (i.e.: inside DSS Stops).

4. Severely contaminated instruments must be cleaned in an ultrasonic unit.

5. Only use solvents intended for stainless steel and always strictly follow the directions for use.

Materials not recommended for stainless steel instruments:

- disinfectants or cleaners containing a high percentage of chlorine,

- disinfectants or cleaners containing oxalic acid.

Not recommended for instruments with colour coding:

 excessively high concentrations of solvents, disinfectants, and cleaning solutions containing the chemicals mentioned above.

Not recommended for titanium components:

All oxidant acids (nitric acid, sulphuric acid, oxalic acid), H2O2! (oxygenated water).

6. Before sterilization, rinse the instruments abundantly with distilled water to eliminate any residues of disinfectant or detergent.



7. Never leave instruments immersed for a long time or store them while they are still moist or wet.

8. After cleaning mechanically or by hand, all surgical instruments must be sterilized.

9. Do not sterilize rusted or corroded instruments.

10. Check all instruments visually. Any worn, blunt or damaged instruments should no longer be used and must be disinfected, cleaned and eliminated.

11. Cutting instruments must be replaced after a maximum of 20 uses.

12. It is recommended not to use hot air sterilizers or glass marble sterilizers as they attain temperatures which may damage the cutting edges and the colour coding. Never exceed 135°C!

13. Check for corrosion after sterilization. The use and sterilization of the instruments may gradually erase the laser markings. Replace the instruments when the markings aren't any more sufficiently visible.

14. It is extremely important to handle all cutting instruments carefully:

- the cutting edges and the drill tips may experience damage, resulting in reduction in their cutting performance, if these hit into metallic bowls or other objects,

- also during surgery, handle cutting instruments "gently", if possible place them in a storage dish filled with demineralised water and avoid dropping them on their tips,

- never allow drills to touch each other while being cleaned in an ultrasonic unit as the cutting edges and the microthread may be damaged!

15. The various instrument packaging may not be sterilized.

SDS Handpiece:

Disassembling the head:

- Unscrew the head nut using the enclosed wrench.
- Remove the tool bearing axis.
- Unscrew the head nut and disassemble the head from the body.
- Remove the internal geared cartridge.

Reassembling the head :

- Insert the tool bearing axis in the head.
- Screw the head nut using the enclosed wrench.
- Insert the geared cartridge, indexing it to the body of the handpiece.
- Assemble the head, indexing it correctly and screwing the nut on the body of the handpiece.

Disinfection:

Disinfect by spray of disinfection cloth only on the surface. Total immersion in a disinfectant solution is not recommended.

Disinfect and sterilize the handpiece before the first use and after each use.

In order to prolong the life of the handpiece, it is recommended to disassemble the head and to rinse it abundantly to remove any remaining physiological liquid. Remember to clean out the internal irrigation canal and the external spray nozzle using the enclosed wire.

Lubrication:

Use lubrication spray before each sterilization. Spray for a maximum of one second. Hold the nozzle firmly in place until the pressure drops. The oil penetrates, cleans and lubricates the instrument completely.

Sterilization:

No trace of disinfectant should remain when sterilizing; all parts must be previously rinsed. Only in the autoclave at 135°C for 20 minutes (time to maintain the temperature). It is advised to use an individual bag for autoclave sterilization.

Soft Dilating System

SDS Box :

The SDS Box is an instrument carrying box composed of a cover, by a base in PPSU and of a working table/calibre in anodized aluminium fitted with holders in PTFE (Teflon).

After unscrewing the two white cylinders holding the table, it may be removed for cleaning and suitable disinfection.

It is possible to separate the cover from the base by enlarging it slightly from the dovetail. Be careful, as frequent such manipulations can weaken the plastic material.

For cleaning of the Box, use non abrasive cleansers and avoid rubbing plastic surfaces with abrasive objects in order to avoid scratches and preserve the glossy appearance.

Concerning disinfectants and detergents, only use specific products intended for aluminium and PPSU and always adhere strictly to the directions for use.

Alkaline detergents with pH >9 are not recommended for anodized aluminium. Values between pH 5 and pH 9 are permitted.

Chemical or hot air sterilizers are not recommended for PPSU.

The SDS Box may be completely sterilized in the autoclave (maximum 135°C).

WARNINGS

THE USE OF THESE INSTRUMENTS IS RESTRICTED TO A DENTIST OR ORAL SURGEON. THE CHOICE OF THE DILATORS FOR THE FORMING OF AN ADEQUATE SEATING FOR IMPLANT IS THE RESPONSIBILITY OF THE PRACTITIONER.

BEFORE USING THESE INSTRUMENTS, APPROPRIATE TRAINING IN THEIR PROPER USE IS STRONGLY RECOMMENDED.

FOLLOW THE INSTRUCTIONS FOR USE.

THE CONTENT OF THE PACKAGES IS NOT STERILE.

ALL COMPLETELY NEW INSTRUMENTS MUST BE SERILIZED WITHOUT PACKAGING BEFORE USE.

ALSO PAY ATTENTION TO THE INSTRUCTIONS IN THE PACKAGING. FOR ADDITIONAL INFORMATION, CONSULT THE WEBSITE www.arsline.com/sds PRESERVE THIS NOTICE AS FUTURE REFERENCE

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Internet Video Tour : www.arsline.com/sds



